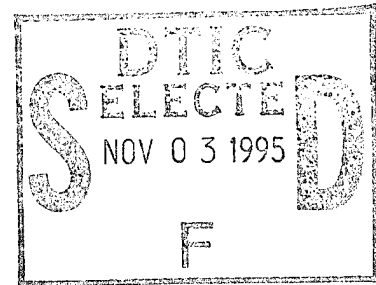


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CONTRACT NUMBER: DAMD17-89-C-9179



TITLE: Regulatory Affairs

PRINCIPAL INVESTIGATOR: Carl R. Morin, Jr.  
Corazon Atienza

CONTRACTING ORGANIZATION: EER Systems, Inc.  
Vienna, VA 22182

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Fort Detrick, Frederick, Maryland 21702-5012

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## REGULATORY AFFAIRS FINAL REPORT

Contract No. DAMD17-89-C-9179

EER SYSTEMS INC.  
1593 Spring Hill Road  
Vienna, Virginia 22182

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## 1.0 INTRODUCTION

The objective of this procurement was to facilitate the timely and efficient execution of the U.S. Army Medical Materiel Development program by providing a mechanism for assembling and preparing both generic and product-specific FDA-related documentation as well as a data management system for determining the status of the documentation. The scope of work required the contractor to furnish the necessary personnel, facilities, equipment, and supplies incident to assembling and preparing Investigational New Drug Exemption (IND), and Investigational New Device Exemption (IDE) applications and IND/IDE-related documentation; preparing and assembling New Drug Applications (NDA), Pre-Market Notifications (510k), Pre-Market Approval applications (PMA), Biological License applications (PLA/ELA), and EPA registration packages; and providing database management for the documentation development. The cost plus fixed fee contract was awarded in September 1989, for a 36-month term with two 12-month option periods.

The U.S. Army Medical Materiel Development Activity (USAMMDA) awarded this multi-year contract to EER Systems Corporation (EER), Vienna, Virginia, and Oxford Research International Corp. (ORIC), Clifton, New Jersey, to provide the requested support. The EER/ORIC team has provided the necessary managerial and technical expertise to complete the support defined in the Statement of Work during the initial contract term (October 1989 to September 1992), two 1-year options (October 1992 to September 1993; October 1993 to September 1994) and three extensions (October 1994 to March 1995; April 1995 to June 1995; and July 1995 to October 1995). This final report summarizes all the work performed under this contract and presents the associated fiscal data.

The report is organized to provide an overall summary of the work performed (2.0 SUMMARY), a detailed description of each task order to include fiscal and planning data (3.0 DESCRIPTION OF WORK PERFORMED), a summary of labor and cost data (4.0 SUMMARIZED WORK AND FISCAL DATA), a discussion of problems encountered together with resolutions developed (5.0 PROBLEMS AND RESOLUTIONS), and conclusions drawn by the contractor (6.0 CONCLUSIONS).

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## 2.0 SUMMARY

The original contract required 42 modifications during 73 months between contract signing and conclusion (September 1989 to October 1995). Twenty-five modifications were required to execute funding changes as the contract grew in value from \$2,724,109 (including two options) to \$4,622,783. The remaining 16 modifications were required for technical or administrative changes. Figure 2.0-1 summarizes contract funding modifications; Attachment 1 provides a detailed list of modifications.

A broad mix of highly skilled and experienced personnel was required to meet the work requirements of the contract. The contractor subcontracted 30.42% of the total contract effort (\$4,394,932) to a combination of large and small contractors and individual consultants. Eighteen percent of the overall contract value (\$801,393) was performed by Oxford Research International Corporation, the originally proposed team member for this solicitation. This subcontracted effort exceeded all the contractor's Small Business and Small Disadvantaged Business Subcontracting Plan objectives.

The contract was executed by issuance of 59 task orders and 97 task order modifications spread over the life of the contract, as indicated in Figure 2.0-2. Attachment 2 provides a detailed listing of task orders with associated modifications and approved funding for each.

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Value of Original Contract	\$1,608,535
Mod 13 — Additional Funds	777,336
Mod 15 — Additional Funds	99,537
Mod 16 — Additional Funds	121,396
Mod 18 — Additional Funds	119,816
<b>Total Base Years' Funds</b>	<b>\$2,726,620</b>
Option Year 1 Funding	627,997
Mod 21 — Additional Funds	147,774
Mod 22 — Additional Funds	68,000
<b>Total Option 1 Year's Funds</b>	<b>\$843,771</b>
Mod 23 — Option Year 2 Funds	247,597
Mod 28 — Incremental Funds	174,390
Mod 30 — Incremental Funds	10,171
Mod 31 — Incremental Funds	38,116
Mod 32 — Incremental Funds	17,303
	<b>\$487,577</b>
Mod 32 — Additional Funds	146,129
Mod 33 — Additional Funds	23,750
Mod 34 — Additional Funds	12,303
Mod 35 — Additional Funds	55,000
	<b>\$237,182</b>
<b>Total Option 2 Years' Funds</b>	<b>\$724,759</b>
Mod 36 — 6-Month Extension Funds	77,625
Mod 38 — Incremental Funds	20,947
Mod 39 — Incremental Funds	34,408
	<b>\$132,980</b>
Mod 39 — Additional Funds	86,425
<b>Total 6-Month Extension's Funds</b>	<b>\$219,405</b>
Mod 40 — 3-Month Extension Funds	67,643
Mod 41 — Additional Funds	80,585
<b>Total 3-Month Extension's Funds</b>	<b>\$148,228</b>
Mod 42 — Additional 3-Month Extension without Funds	
<b>TOTAL AMOUNT OF CONTRACT</b>	<b>\$4,662,783</b>

**Figure 2.0-1: The Contract Grew  
Considerably Through Contract Funding  
Modifications.**

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WORK FLOW		
CONTRACT YEAR	NEW TASKS ASSIGNED	TASK MODIFICATION (INCREASED)
Year 1 (Oct '89 - Sep '90)	12	1
Year 2 (Oct '90 - Sep '91)	15	19
Year 3 (Oct '91 - Sep '92)	22	21
Year 4 (Oct '92 - Sep '93)	3	18
Year 5 (Oct '93 - Sep '94)	7	15
6-Month Extension (Oct '94 - Mar '95)	0	12
3-Month Extension (Apr '95 - June '95)	0	10
3-Month Extension (July '95 - Sep '95)	0	1

**Figure 2.0-2: The Contract Was Executed Through 59 Task Orders and 97 Task Order Modifications.**



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## 3.0 DESCRIPTION OF WORK PERFORMED

Figure 3.0-1 summarizes the types of tasks completed, categorized, and identified in the scope of work. The following paragraphs describe each task, including labor and financial data.

### 3.1 Task Order 89-001

#### 3.1.1 Requirement

Task 89-001 required the development and maintenance of a planning, coordination, and task integration infrastructure for the Regulatory Affairs Contract. The infrastructure provides for overall project planning and tracking, individual task planning, monthly project review, and meeting minutes, as required; monthly and quarterly progress reports and a final report; and attendance at relevant professional meetings and symposia.

#### 3.1.2 Accomplishment

EER hired well-qualified personnel and consultants to provide the required support for this contract and developed and maintained a cost and schedule tracking system to assist in the preparation of monthly and quarterly reports. EER established and maintained an inventory control system to account for property furnished by the Government and/or purchased under this contract. We have submitted DD Form 1662 to Mr. Craig Lebo, USAMRAA's Property Custodian, reporting yearly the total quantity and dollar value of each government property furnished or purchased under this contract. EER also established and maintained a central filing system for all regulatory affairs related documents. The file was maintained in the Regulatory Affairs (RA) Library.

#### 3.1.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total Manhours Expended	10,628 (as of 28 July 1995)
Total Funds Approved	\$704,648
Total Funds Expended	\$665,937
Percent of Approved Funds Expended	94.51%

### 3.2 Task Order 89-002

#### 3.2.1 Requirement

This task required the maintenance of a data management system to support the preparation, tracking, and reporting of IND, NDA, IDE, 510(k), PMA, PLA and ELA documents

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for the Project Management Divisions. The system consisted of four components. First, a filing subsystem stores hard copies of all regulatory affairs documents; all documents are filed by IND/NDA/ PLA/PMA/510(k) number and subject. Second, a computerized file tracking and control subsystem locates, checks out, and returns documents to the library; this subsystem records the location of documents. Third, an on-line database contains a description and the current status regarding the preparation of each regulatory document; the database will have data field search and cross-reference capabilities. Fourth, a reporting subsystem summarizes the status of the preparation effort for each regulatory document; this subsystem supports the preparation of annual and quarterly cumulative summary status reports for all regulatory documents.

## **3.2.2 Accomplishment**

EER developed, maintained, and upgraded the data management system that supported the preparation and submission of IND/NDA/PLA/ELA and other regulatory affairs documentation; prepared and submitted periodic backup of the system together with a listing of all regulatory affairs documents filed in the library; responded to USAMMDA's request of copying the backup system to a 3 1/2" high density diskette and provided written instructions to properly restore the database.

## **3.2.3 Fiscal and Planning Data**

Labor and financial data for this task are summarized below.

Total Manhours Expended	4,381
Total Funds Approved	\$218,508
Total Funds Expended	\$204,403
Percent of Approved Funds Expended	93.54%

## **3.3. Task Order 90-003**

### **3.3.1 Requirement**

This task required the collection, organization, and evaluation of pertinent regulatory affairs data for the preparation and submission of Office of The Surgeon General-sponsored IND annual progress reports.

### **3.3.2 Accomplishment**

EER collected, copied, organized, and assessed regulatory affairs documentation for preparation and submission of annual reports. Table 3.3.2.1 lists annual reports prepared and submitted for each contract and option years, including contract extensions. Table 3.3.2.2 provides a list of IND drug names that we prepared and for which we submitted annual reports.

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**Table 3.3.2.1: Annual Reports Prepared and Submitted.**

Contract Year	Number of Annual Reports Submitted By Project Management Division	
	Pharmaceuticals	Biologics
Year 1 (14 Mar 90 - 28 Sep 90)	8	0
Year 2 (29 Sep 90 - 28 Sep 91)	15	4
Year 3 (29 Sep 91 - 28 Sep 92)	12	4
Option 1 (29 Sep 92 - 28 Sep 93)	12	1
Option 2 (29 Sep 93 - 28 Sep 94)	14	2
6-Month Extension (29 Sep 94 - 31 Mar 95)	7	0
3-Month Extension (1 Apr - 30 Jun 95)	5	2
1-Month Extension (1 - 30 Jul 95)	1	1

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**Table 3.3.2.2: List of Products For Which We Prepared Annual Reports.**

IND No.	Drug Name	Indication	FDA Anniversary Date	Date of Last AR Submitted
<b>PHARMACEUTICAL</b>				
8,990	Mefloquine (WR 142,490)	Antimalarial	3 Jul 1972	31 Jul 1995
9,847	Halofantrine	Antimalarial	11 Jun 1973	30 Jun 1995
14,150	Pentostam (WR 229,870)	Antileishmanial	2 Feb 1978	16 Feb 1995
16,666	Ribavirin	Antiviral	26 Sep 1979?	11 Oct 1994
21,084	WR 6,026	Antileishmanial	10 Nov 1982	8 Dec 1994
23,509	Pyridostigmine Bromide	Antidote	2 Feb 1984	16 Feb 1995
26,740	Ketoconazole	Antileishmanial	29 Sep 1987	15 Jul 1992
27,503	Atropine Sulfate	Antidote	27 Nov 1985	29 Nov 1994
28,301	Atropine Injection & Pralidoxime Chloride	Antidote	30 Apr 1986	12 Apr 1995
30,726	Ketoconazole vs. Pentostam	Antileishmanial	29 Sep 1987	21 Oct 1992
30,899	Pyridostigmine Bromide-Sustained Release	Antidote	1 Dec 1987	29 Nov 1994
33,272	Niclosamide Lotion	Antischistosomal	(9?) Jun 1989	11 May 1995
35,291	Multi Shield Topical Skin Protectant	Topical skin protectant from exposure to nitrogen mustard agent	2 Oct (19??)	18 Sep 1991
38,503	WR 238605 Succinate	Antimalarial	19 Dec 1991	8 Feb 1995
45,464	Azithromycin Dihydrate	Prophylaxis/treatment for malaria	8 Jun 1994	30 Jun 1995

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**Table 3.3.2.2 (Continued): List of Products For Which We Prepared Annual Reports.**

IND No.	Drug Name	Indication	FDA Anniversary Date	Date of Last AR Submitted
<b>BIOLOGICS</b>				
1332	Botulism-Immune Plasma (Human)	Botulism	10 Aug 1978	13 Jul 1995
2334	<i>P. falciparum</i> Circumsporozoite Recombinant <i>E. coli</i>	Antimalarial	27 Feb 1986	13 Feb 1991
2420	<i>Klebsiella</i> capsular Polyvalent Polysaccharide Vaccine	Prevent <i>Klebsiella</i> Infections	24 Jul 1986	31 Aug 1992
2569	<i>Pseudomonas aeruginosa</i> O-polysaccharide Toxin A Conjugate Vaccine, Polyvalent	Prevent <i>Pseudomonas</i> Infections	18 Mar 1987	31 Aug 1992
3117	<i>P. falciparum</i> Circumsporozoite Recombinant antigen	Antiviral	4 Jan 1989	12 Dec 1990
3388	<i>Klebsiella</i> Capsular Polysaccharide	Prevent Nosocomial infections due to <i>Pseudomonas aeruginosa</i> and <i>Klebsiella</i> spp.	4 Jan (19??)	19 Feb 1992
3723	Pentavalent (ABCDE) Botulinum Toxoid, Aluminum Phosphate Adsorbed	Prevent botulism	23 Oct 1990	15 May 1995
3842	V. Cholerae	Prevent cholera	31 Jan 1991	19 Feb 1992
4179	Shigella Vaccine	Prevent Shigella infection/bacillary dysentary	25 Sep 1991	19 Jan 1994
4510	Enterotoxigenic <i>E. coli</i> CFA/II Encapsulated in Biodegradable Microspheres	Protect against enterotoxigenic <i>E. coli</i> diarrhea	17 Apr 1992	28 Oct 1993
5077	Clostridium Botulinum Type F Toxoid Vaccine	Immunization against botulinum F intoxication	20 Apr 1992	15 May 1995

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## 3.3.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total Manhours Expended	4,295
Total Funds Approved	\$279,573
Total Funds Expended	\$260,512
Percent of Approved Funds Expended	93.18%

## 3.4 Task Order 90-004

### 3.4.1 Requirement

Task Order 90-04 required EER to provide follow-up support for a New Drug Application (NDA) for atropine sulfate aerosol inhaler that was submitted to the FDA on 6 February 1990.

### 3.4.2 Accomplishment

EER planned, managed, and coordinated the efforts for this task. EER secured the services of 3M Pharmaceuticals (subcontractor) to provide support associated with the NDA application. Periodic progress reports were telephonically provided to USAMMDA. An NDA amendment addressing deficiencies in the chemistry and microbiology section was prepared and submitted to the FDA on 26 November 1991.

## 3.4.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	47.5 (3M level labor hours not available)
Total Funds Approved	\$207,323
Total Funds Expended	\$124,348
Percent of Approved Funds Expended	60%

## 3.5 Task Order 90-005

### 3.5.1 Requirement

This task required the preparation of an Investigational New Drug (IND) application for Lassa Fever Immune Globulin.

### 3.5.2 Accomplishment

This task was initiated on 3 May 1990 and cancelled by USAMRAA on 6 May 1992 due to insufficiency of the materials for the preclinical section of the IND application. Prior to the

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cancellation of the task, EER met and coordinated with the USAMMDA Product Manager in developing a timetable for IND preparation. This timetable was submitted to USAMMDA on 14 May 1990.

## 3.5.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	117.5
Total Funds Approved	\$40,972
Total Funds Expended	\$11,424
Percent of Approved Funds Expended	28%

## 3.6 Task Order 90-006

### 3.6.1 Requirement

This task required EER to prepare an IND application for the Immune Enhancer Poly-(ICLC), to support clinical trials as a prophylactic to prevent viremia or its symptoms.

### 3.6.2 Accomplishment

This task was initiated on 27 April 1990 and cancelled by USAMRAA on 11 September 1991 due to the cancellation of the program. Prior to the task cancellation, EER critically reviewed and analyzed data and provided the Product Manager a list of the data needed to complete preparation of the IND; met with the USAMMDA Product Manager to resolve regulatory issues; and prepared and submitted two working drafts of the IND (16 August 1990 and 17 February 1991) for USAMMDA review and comments.

### 3.6.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	292
Total Funds Approved	\$40,972
Total Funds Expended	\$28,770
Percent of Approved Funds Expended	70.22%

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## 3.7 Task Order 90-007

### 3.7.1 Requirement

This task required EER to revise and update two Investigator's Brochures for products tested under BB-IND 3388: Human Serum Albumin, the placebo, and Klebsiella/Pseudomonas intravenous Immunoglobulin, Hyperimmune, Nosocuman<sup>TM</sup>, the test product.

### 3.7.2 Accomplishment

Two final Investigator's Brochures for Human Serum Albumin 0.5% (wt/vol) and for Klebsiella/Pseudomonas Intravenous Immunoglobulin (IVIG), including an IBM-compatible diskette in WordPerfect format, were submitted to USAMMDA on 25 July 1990.

### 3.7.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	33
Total Funds Approved	\$6,250
Total Funds Expended	\$2,851
Percent of Approved Funds Expended	45.62%

## 3.8 Task Order 90-008

### 3.8.1 Requirement

The initial requirement for this task was for EER to review manufacturing and clinical information and prepare amendments to BB-INDs 1952 (Dengue 1, 45AZ5) and 2675 (Dengue 4, 341750 CARIB); however, as a result of USAMMDA's discussion with the FDA regarding this submission, it was agreed that two new IND applications should be submitted. This task, and the initial requirement, were modified on 12 December 1990 (Mod 1).

### 3.8.2 Accomplishment

EER prepared and submitted two final IND applications for Dengue 1 and 4 to USAMMDA on 31 December 1990. Both IND applications were filed with the FDA and were assigned BB-IND 3818 (Dengue 1) and IND 3819 (Dengue 4) with an FDA anniversary date of 2 January 1991.



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## 3.8.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	301.5
Total Funds Approved	\$25,791
Total Funds Expended	\$24,660
Percent of Approved Funds Expended	95.61%

## 3.9 Task Order 90-009

### 3.9.1 Requirement

This task required EER to assemble and prepare an IND application for AVPox Vectored Rabies Vaccine. The task included writing the Introductory Statement and Investigator's Brochure and formatting the table of contents.

### 3.9.2 Accomplishment

EER wrote and finalized the Introductory Statement and Investigator's Brochure, formatted the table of contents, reviewed and analyzed materials provided for inclusion in the IND application, attended coordination meetings, participated in a pre-IND meeting with the FDA, and prepared and submitted a final IND application on 26 April 1991. The IND application was filed with the FDA and was assigned BB-IND 3923.

## 3.9.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	184
Total Funds Approved	\$34,978
Total Funds Expended	\$15,410
Percent of Approved Funds Expended	44%

## 3.10 Task Order 90-010

### 3.10.1 Requirement

This task required EER to assemble an IND application for Botulism Anti-toxin F(ab)<sub>2</sub> Fragment, Sera Type A-G, Equine. The task included writing the Introductory Statement and Investigator's Brochure and formatting the table of contents.

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## 3.10.2 Accomplishment

EER wrote and finalized the Introductory Statement and Investigator's brochure, formatted the table of contents, reviewed and analyzed materials provided for inclusion in the IND application, attended coordination meetings, participated in a pre-IND meeting with the FDA, and prepared and submitted a final IND application on 11 October 1990. The IND application was filed with the FDA and was assigned BB-IND 3703, FDA anniversary date 11 October 1990.

## 3.10.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	186
Total Funds Approved	\$32,362
Total Funds Expended	\$11,994
Percent of Approved Funds Expended	\$37%

## 3.11 Task Order 90-011

### 3.11.1 Requirement

This task required the preparation of an IND for a Liposome Encapsulated repeatless malaria vaccine.

### 3.11.2 Accomplishment

This task was initiated on 26 October 1990 and was cancelled by USAMRAA on 13 December 1990 because the manufacturer, Smith Kline Beecham, asked to prepare the IND in their own regulatory affairs department.

### 3.11.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	3.5
Total Funds Approved	\$16,047
Total Funds Expended	\$86
Percent of Approved Funds Expended	0.54%

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## 3.12 Task Order 90-012

### 3.12.1 Requirement

This task required EER to prepare an IND for Tissue Culture Derived Vaccinia Vaccine (New Improved Smallpox Vaccine).

### 3.12.2 Accomplishment

This task was initiated on 20 October 1990 and completed on February 1993. It took EER more than 2 years to complete this IND because of several factors: available information was changed several times, the protocol was not finalized until October 1992, there have been changes in the study plan, a considerable amount of information was made available only after the death of Dr. Dalrymple in July 1992, and there were changes in the USAMRIID personnel (three different Principal Investigators and three different Product Managers) during the conduct of this effort. These problems added to EER's difficulties in interpreting and assembling necessary data. Despite all these obstacles, a final IND was assembled and delivered to USAMMDA on 18 February 1993. This IND was filed with the FDA and was assigned BB-IND 4984, FDA anniversary date 24 February 1993.

### 3.12.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	614.5
Total Funds Approved	\$43,572
Total Funds Expended	\$44,231
Percent of Approved Funds Expended	101.5%

## 3.13 Task Order 91-013

### 3.13.1 Requirement

EER was initially tasked to assemble an application IND for Lipid A Analog Vaccine on 12 December 1990; however, on 14 May 1991, the task was modified to reflect a submission for a C-1 vaccine, a linked hapten via an aminopropyl spacer to succinylated diphtheria toxoid.

### 3.13.2 Accomplishment

EER prepared and delivered to USAMMDA an IND for C-1 vaccine on 1 August 1991. The IND application was filed with the FDA and was assigned BB-IND 4144. This submission was put on clinical hold by the FDA on 25 September 1991 pending submission of additional information. A modification (Mod 2) was issued by USAMRAA on 29 November 1991 for EER to prepare a response to the questions posed by the FDA on the manufacturing and preclinical

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section of the IND. EER prepared and submitted a response to FDA questions in the form of an IND amendment on 24 January 1992. The clinical hold was lifted on 27 March 1992.

## 3.13.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	470
Total Funds Approved	\$32,585
Total Funds Expended	\$31,906
Percent of Approved Funds Expended	97.92%

## 3.14 Task Order 91-014

### 3.14.1 Requirement

This task required EER to prepare an IND application for *Shigella* Vaccine, *E. coli/Shigella flexneri 2a (Number 2)*, *EcSf-2a-2*. The goal of this IND was to support Phase 1 and 2 clinical trials of the vaccine in a controlled clinical environment and in the field.

### 3.14.2 Accomplishment

EER prepared and submitted a working draft of the IND on 27 March 1991. EER also participated in a pre-IND meeting with the FDA on 19 April 1992 and took minutes of the meeting. A final IND was delivered to USAMMDA on 1 August 1991. The IND was filed with the FDA and was assigned BB-IND 4179 with an FDA anniversary date of 25 September 1991.

## 3.14.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	262.5
Total Funds Approved	\$23,424
Total Funds Expended	\$20,688
Percent of Approved Funds Expended	88.32%

## 3.15 Task Order 91-015

### 3.15.1 Requirement

This task required EER to assemble an IND application for *Clostridium Botulinum* F Toxoid Vaccine, suitable for submission to the FDA. The task included writing the Introductory Statement and the Investigator's Brochure and formatting the table of contents.

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## 3.15.2 Accomplishment

EER provided USAMMDA a working draft of the Investigator's Brochure on 21 December 1990 and a working draft of the IND on 17 January 1991. A final IND was delivered to USAMMDA on 15 April 1993 and was filed with the FDA and assigned IND 5077. EER also prepared an annual report for this IND under Task Order No. 90-03. This report was submitted to the FDA on 19 May 1995 under Serial No. 008.

## 3.15.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	488
Total Funds Approved	\$45,776
Total Funds Expended	\$44,100
Percent of Approved Funds Expended	96.33%

## 3.16 Task Order 91-016

### 3.16.1 Requirement

This task required EER to assemble an IND application for HANTAVAX, a formalin inactivated vaccine for Hemorrhagic Fever with Renal Syndrome, suitable for submission to the FDA.

### 3.16.2 Accomplishment

This task was initiated on 2 January 1991 and was cancelled by USAMMDA on 31 July 1992 because the manufacturer of the vaccine could not meet current Good Manufacturing Practices (cGMP) requirements. The only deliverable EER prepared and submitted to USAMMDA on 12 March 1991 was a pre-IND briefing package for submission to the FDA.

### 3.16.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	36
Total Funds Approved	\$24,378
Total Funds Expended	\$3,966
Percent of Approved Funds Expended	16.27%

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## **3.17 Task Order 90-017**

### **3.17.1 Requirement**

This task required EER to assemble an IND application for Rift Valley Fever Vaccine, Live, Attenuated, Mutagenized ZH548, MP-12 Strain, Lot 7-2-888, TSI-GSD 223. The task included writing the Introductory Statement and the Investigator's Brochure and formatting the table of contents.

### **3.17.2 Accomplishment**

EER wrote and finalized the Introductory Statement and the Investigator's Brochure; prepared the remaining components of the IND; formatted the table of contents; and prepared and submitted on 27 November 1991 a final IND application. This IND was filed with the FDA and was assigned BB-IND 4037.

### **3.17.3 Fiscal and Planning Data**

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	372
Total Funds Approved	\$33,933
Total Funds Expended	\$30,918
Percent of Approved Funds Expended	91.11%

## **3.18 Task Order 91-018**

### **3.18.1 Requirement**

This task required EER to prepare a "Paper" New Drug Application (NDA) for Sodium Thiosulfate (an antidote for cyanide poisoning). This task involved the gathering and review of all references, articles, and other materials available in U.S. Army Medical Research Institute of Chemical Defense (USAMRIID) databases for sodium thiosulfate.

### **3.18.2 Accomplishment**

EER gathered and reviewed all references, articles, and other available materials retrieved from USAMRIID databases and assembled and submitted a final "Paper" NDA for Sodium Thiosulfate to USAMMDA on 20 March 1991. The "Paper" NDA was filed with the FDA and was assigned NDA 20-166.

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## 3.18.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	266.5
Total Funds Approved	\$20,643
Total Funds Expended	\$17,795
Percent of Approved Funds Expended	86.20%

## 3.19 Task Order 90-019

### 3.19.1 Requirement

This task required EER to assemble and prepare an IND application for Dengue Type 2, S16803 suitable for submission to the FDA.

### 3.19.2 Accomplishment

EER reviewed the manufacturing data; met with the Product Manager to coordinate preparation of the IND; and prepared and delivered a final IND for Dengue-2, S16803 to USAMMDA on 10 July 1991. This IND was filed with the FDA and was assigned BB-IND 4067 with an FDA anniversary date of 15 July 1991.

## 3.19.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	143
Total Funds Approved	\$16,633
Total Funds Expended	\$11,617
Percent of Approved Funds Expended	69.84%

## 3.20 Task Order 91-020

### 3.20.1 Requirement

This task required EER to prepare and assemble Section 7 (Chemistry, Manufacturing and Control Data), Section 8 (Pharmacology and Toxicology data), and Section 9 (Previous Human Experience) of the IND application for Microencapsulated Antibiotic, Ampicillin, Dental.

### 3.20.2 Accomplishment

EER participated in a meeting held at Southern Research Institute on 31 May 1991 and discussed preclinical, clinical, and manufacturing data required to complete Sections 7, 8, and 9

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of the Microencapsulated Ampicillin IND. Minutes of the meeting were prepared and submitted to USAMMDA on 24 June 1991. This task was cancelled by USAMMDA on 1 May 1992. The manufacture of Microencapsulated Ampicillin and completion of the pre-clinical studies were to have been contracted and the contractor was required to prepare and submit the IND application.

## 3.20.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	66
Total Funds Approved	\$21,603
Total Funds Expended	\$6,164
Percent of Approved Funds Expended	28.53%

## 3.21 Task Order 91-021

### 3.21.1 Requirement

This task required EER to assemble an IND application for Lipid A Analog Vaccine C-6 Conjugate. The task included writing the Introductory Statement and the Investigator's Brochure.

### 3.21.2 Accomplishment

EER prepared and delivered to USAMMDA an IND for Gentiobiose Heptaacetate C-6 Conjugate Vaccine on 1 August 1991. The IND was filed with the FDA and was assigned IND 4143. This filing was put on clinical hold by the FDA on 25 September 1991, subject to submission of additional information. A modification (Mod 2) was issued by USAMRAA on 20 November 1991 for EER to prepare a response to the questions posed by the FDA on the manufacturing and preclinical section of the IND. EER prepared a response to FDA questions in the form of an IND amendment that was submitted to USAMMDA on 24 January 1992. The clinical hold was lifted by the FDA on 27 March 1992.

### 3.21.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	282.5
Total Funds Approved	\$20,441
Total Funds Expended	\$19,093
Percent of Approved Funds Expended	93.40%



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## 3.22 Task Order 91-022

### 3.22.1 Requirement

This task required EER to conduct Postmarketing Surveillance of Adverse Drug Events for Inhalation Atropine (NDA 20-056) and Diazepam Autoinjector (NDA 20-124). The task included a monthly literature search of MEDLINE, TOXLINE, AND TOXLIT online databases for abstracts of suspected Adverse Drug Events (ADE); submission of a written review of abstracts of suspected ADE (labelled "serious" and "unexpected"); periodic reporting of adverse drug experience reports at quarterly intervals; and submission of annual reports for both NDAs.

### 3.22.2 Accomplishment

EER conducted a monthly literature search of the automated databases (MEDLINE, TOXLINE, and TOXLIT); reviewed and analyzed abstracts of materials retrieved; prepared monthly abstract reports describing any suspected adverse drug events (ADE) associated with Inhalation Atropine and Diazepam Autoinjector; and submitted annual reports for both INDs prior to their FDA anniversary dates. EER also prepared 15-Day Alert Reports on abstracts that described a "serious" and "unexpected" ADE. Additionally, we have obtained FDA approval to submit 15-Day Alert Reports using our EER computer-generated form to facilitate reporting of adverse events for both products.

### 3.22.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	1,266
Total Funds Approved	\$82,240
Total Funds Expended	\$71,959
Percent of Approved Funds Expended	87.5%

## 3.23 Task Order 91-23

### 3.23.1 Requirement

This task required EER to review and assemble an IND application for for SPf66 Recombinant Malaria Blood Stage Vaccine. The task included writing the Introductory Statement and preparing a pre-IND briefing package that included an Investigator's Brochure and a clinical investigational plan for submission to the FDA.

### 3.23.2 Accomplishment

EER reviewed and analyzed information received from USAMMDA for the IND; prepared and submitted a list of additional materials needed; coordinated with the manufacturer of the

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product with USAMMDA's approval in obtaining missing data; and prepared and assembled an IND suitable for submission to the FDA. A final IND application, including an IBM-compatible diskette copy, was submitted on 28 July 1992. The IND was filed with the FDA and was assigned BB-IND 4668, with an FDA anniversary date of 7 August 1992.

## 3.23.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	332
Total Funds Approved	\$25,832
Total Funds Expended	\$23,769
Percent of Approved Funds Expended	92%

## 3.24 Task Order 91-024

### 3.24.1 Requirement

This task required EER to review and assemble information for an IND for Pfs 25 Recombinant Protein Transmission blocking malaria vaccine. The task included writing the Introductory Statement and preparing a pre-IND briefing package that included an Investigator's Brochure and a clinical investigational plan for submission to the FDA.

### 3.24.2 Accomplishment

This task was initiated on 5 September 1991 and was cancelled by USAMRAA on 23 July 1992. EER was notified that NIH will assemble the IND application.

### 3.24.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	9
Total Funds Approved	\$25,832
Total Funds Expended	\$661
Percent of Approved Funds Expended	2.56%

## 3.25 Task Order 91-25

### 3.25.1 Requirement

This task required EER to expeditiously prepare an FDA-approvable Premarket Approval Application (PMA) for the exclusive military use of a Resuscitation Fluids Production System (REFLUPS).

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## 3.25.2 Accomplishment

EER planned and coordinated the effort and also secured the services of Oxford Research International Corporation (subcontractor) to provide support for this task. A final PMA application was delivered to the FDA on 8 December 1992, and was assigned PMA #920054. In conjunction with the application, EER also submitted to the FDA PMA Amendment number 001 that provided summaries and results of three reports not previously included in the original submission. Post-submission support for this task was cancelled by USAMMDA on 14 January 1994 because the Government was no longer interested in securing PMA approval of the above-mentioned device.

## 3.25.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	8,107
Total Funds Approved	\$765,142
Total Funds Expended	\$740,563
Percent of Approved Funds Expended	96.79%

## 3.26 Task Order 91-026

### 3.26.1 Requirement

This task required EER to review available data provided by USAMMDA and prepare an IND application for Enterotoxigenic *E. coli* Vaccine. The task included writing the Introductory Statement, the General Investigational Plan, and the Investigator's Brochure.

### 3.26.2 Accomplishment

EER reviewed all materials received; met and coordinated the effort with the USAMMDA Product Manager; and prepared and assembled an IND suitable for submission to the FDA. A final IND was submitted to USAMMDA on 7 April 1992. The IND was filed with the FDA and was assigned BB-IND 4510 with an FDA anniversary date of 17 April 1992.

### 3.26.3 Fiscal and Financial Data

Summary of labor and financial data for this task are as follows:

Total EER Manhours Expended	315
Total Funds Approved	\$23,241
Total Funds Expended	\$21,814
Percent of Approved Funds Expended	93.86%

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## 3.27 Task Order 91-027

### 3.27.1 Requirement

This task required EER to assemble an IND application for Dengue 2 (16681) PDK-53. The task included reviewing available supporting literature, retrieving additional articles, and analyzing information gathered. EER was also tasked to write the Introductory Statement, in collaboration with Dr. Hoke of WRAIR, and to format the table of contents.

### 3.27.2 Accomplishment

EER critically reviewed available materials; conducted a literature search of the electronic databases; retrieved and analyzed additional articles; wrote and finalized the Introductory Statement and other components of the IND; formatted the table of contents; and prepared and submitted a final IND on 30 January 1992. The IND was filed with the FDA and was assigned BB-IND 4394 with the an FDA anniversary date of 5 February 1992.

### 3.27.3 Fiscal and Financial Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	215
Total Funds Approved	\$16,487
Total Funds Expended	\$15,314
Percent of Approved Funds Expended	92.89%

## 3.28 Task Order 92-028

### 3.28.1 Requirement

This task required EER to review and assemble the investigational plan, clinical protocol, and manufacturing, quality control, and preclinical testing data for an amendment to BB-IND 3233, *Plasmodium falciparum* Circumsporozoite Antigen Vaccine Liposome Encapsulated.

### 3.28.2 Accomplishment

EER reviewed all data received for completeness and compliance with the current FDA regulations and prepared an IND Amendment to BB-IND 3233. The final IND Amendment was submitted to USAMMDA on 8 July 1992 for submission to the FDA.

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## 3.28.3 Fiscal and Financial Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	97
Total Funds Approved	\$8,129
Total Funds Expended	\$7,324
Percent of Approved Funds Expended	90.10%

## 3.29 Task Order 92-029

### 3.29.1 Requirement

This task required EER to assemble and prepare an IND application for Q-fever Whole Cell Vaccine (TSI-GSD-224) and its companion skin test antigen (TSI-GSD-225).

### 3.29.2 Accomplishment

EER reviewed all documents received from USAMMDA; conducted a literature search of electronic databases; retrieved and analyzed additional reference materials needed to complete the preparation of the IND; and prepared and submitted the final IND, as well as an IBM-compatible diskette copy, for the above product to USAMMDA on 10 July 1992. The IND was filed with the FDA and was assigned BB-IND 4644 with an FDA anniversary date of 21 July 1992.

## 3.29.3 Fiscal and Financial Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	217.5
Total Funds Approved	\$15,187
Total Funds Expended	\$14,470
Percent of Approved Funds Expended	95.28%

## 3.30 Task Order 92-30

### 3.30.1 Requirement

This task required EER to prepare a summary of side effects associated with pyridostigmine during the Operation Desert Storm/Shield.

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## 3.30.2 Accomplishment

EER developed a matrix for display of questionnaire responses provided by participants in Operation Desert Storm/Shield. EER arrayed the data obtained and tabulated the results and provided a summary with comments. EER also prepared a report summarizing the use and side effects of pyridostigmine bromide for submission to the FDA. The report was submitted to the FDA on 27 May 1992 under Serial No. 029 as an information amendment. This report was also integrated in the Pyridostigmine Bromide NDA prepared and submitted under Task No. 94-57.

## 3.30.3 Fiscal and Financial Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	124.5
Total Funds Approved	\$7,809
Total Funds Expended	\$6,498
Percent of Approved Funds Expended	83.21%

## 3.31 Task Order 92-031

### 3.31.1 Requirement

This task required the contractor to critically review the WR 238605 Succinate IND application for completeness and format the IND application suitable for submission to the FDA.

### 3.31.2 Accomplishment

EER critically reviewed all sections of the IND; formatted the table of contents and organized the materials suitable for submission to the FDA; and assembled and submitted to USAMMDA a final IND on 16 December 1991. The IND was filed with the FDA and was assigned IND #38,503 with an FDA anniversary date of 19 December 1991.

### 3.31.3 Fiscal and Financial Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	122.5
Total Funds Approved	\$9,185
Total Funds Expended	\$6,831
Percent of Approved Funds Expended	74.37%

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## 3.32 Task Order 92-032

### 3.32.1 Requirement

This task required EER to assemble an IND application for Enterotoxigenic *E. coli* Vaccine, Whole Cell/B Subunit. This task included writing the Introductory Statement and the Investigator's Brochure, formatting the table of contents, and obtaining the services of an expert in the field of enteric vaccine development to conduct scientific and regulatory review of manufacturing and clinical data and protocol.

### 3.32.2 Accomplishment

EER wrote and finalized the Introductory Statement, Investigator's Brochure, and other components of the IND; formatted the table of contents; obtained the services of an expert consultant in the field of enteric vaccine from the University of Virginia; and prepared and submitted a working draft of the IND on 20 August 1993 for USAMMDA review and comments. The working draft submitted was finalized by USAMMDA and submitted to the FDA and was assigned BB-IND 5253 with an FDA anniversary date of 13 September 1993.

### 3.32.3 Fiscal and Financial Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	190.5
Total Funds Approved	\$24,884
Total Funds Expended	\$17,045
Percent of Approved Funds Expended	68.5%

## 3.33 Task Order 92-033

### 3.33.1 Requirement

This task required EER to prepare official submissions (protocols, manufacturing data, pharmacology, toxicology, and clinical data and Investigators' Brochure) for an amendment to BB-IND 3842 Cholera Vaccine Whole/B subunit and *E. coli* K/13 Placebo.

### 3.33.2 Accomplishment

EER critically reviewed provided protocols, manufacturing data, pharmacology, toxicology and clinical studies; secured the services of an expert in the field of enteric vaccine development from the University of Virginia to review the adequacy of the protocol and data gathered for the IND amendment; and prepared and submitted a final Investigator's Brochure including a final chemistry, manufacturing and control data section.

# DRAFT

## 3.33.3 Fiscal and Financial Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	183
Total Funds Approved	\$14,312
Total Funds Expended	\$13,217
Percent of Approved Funds Expended	92.35%

## 3.34 Task Order 92-034

### 3.34.1 Requirement

This task required EER to prepare official submissions (protocols, manufacturing data, pharmacology, Investigator's Brochure, investigational plan, and clinical data) for an amendment to BB-IND 4179, Shigella Vaccine (EcSf2a2).

### 3.34.2 Accomplishment

This task was initiated on 8 January 1992 and was cancelled by USAMRAA on 2 April 1993 because USAMMDA no longer considered the amendment necessary.

## 3.34.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	30
Total Funds Approved	\$14,060
Total Funds Expended	\$2,750
Percent of Approved Funds Expended	19.56%

## 3.35 Task Order 92-035

### 3.35.1 Requirement

This task required EER to analyze USAMRDC's regulatory compliance system with regard to applicable Federal Regulations, specifically 21 CFR 312 and 314. The task included determining the status of compliance of individual USAMRDC clinical laboratories with both 21 CFR 312 and 314, and the USAMRDC regulatory compliance system, and after determining USAMRDC's compliance system, identifying the strengths and weakness of the system and presenting alternative solutions or methods for achieving compliance with the CFRs.



# DRAFT

## 3.35.2 Accomplishment

EER conducted a current Good Clinical Practice (cGCP) compliance evaluation of seven USAMRMC research laboratories including those in Kenya and Thailand. This evaluation led to major recommendations for improvement of procedures. These improvements are being promulgated through the development of regulatory guidance and an accompanying book of procedures.

## 3.35.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	2,296.5
Total Funds Approved	\$264,970
Total Funds Expended	\$253,790
Percent of Approved Funds Expended	95.78%

## 3.36 Task Order 92-036

### 3.36.1 Requirement

This task required EER to assemble an IND application for Enterotoxigenic *E. coli* and *Shigella sp.* Milk Immunoglobulin Concentrate (ETEC/Shg MIC), respond to FDA questions, and prepare amendments. The task included attending a pre-Phase I/II meeting at FDA, preparing meeting summary notes, preparing final responses to FDA questions, and incorporating FDA comments into regulatory documents.

### 3.36.2 Accomplishment

This task was initiated on 9 April 1992 and cancelled by USAMRAA on 23 July 1992 due to the unsuitability of the current formulation of 30 tablets, 3x a day.

## 3.36.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	104.5
Total Funds Approved	\$38,367
Total Funds Expended	\$8,153
Percent of Approved Funds Expended	21.25%

# DRAFT

## 3.37 Task Order 92-037

### 3.37.1 Requirement

This task required EER to review and assemble an IND application for Dengue 2, 16681 PDK-53, 40, and 11. The task included writing the Introductory Statement and preparing the Investigator's Brochure, similar to BB-IND 4394.

### 3.37.2 Accomplishment

EER prepared and submitted to USAMMDA on 7 May 1992 an IND application for Dengue 2. The IND was filed with the FDA and was assigned BB-IND 4546. USAMMDA withdrew the IND application on 14 December 1992.

### 3.37.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	112
Total Funds Approved	\$8,633
Total Funds Expended	\$6,459
Percent of Approved Funds Expended	74.82%

## 3.38 Task Order 92-038

### 3.38.1 Requirement

This task required EER to assemble an IND application for Dengue 3 CH53489 PDK-30, 30, and 10. The task included writing the Introductory Statement, formatting the table of contents, and preparing the Investigator's Brochure similar to that of IND 4067.

### 3.38.2 Accomplishment

EER wrote and finalized the Introductory Statement, Investigator's Brochure, and other components of the IND; formatted the table of contents; and prepared and submitted a final IND for the above product to USAMMDA on 13 May 1992. The IND was filed with the FDA and was assigned BB-IND 4552 with an FDA anniversary date of 13 May 1992.

# DRAFT

## 3.38.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	62
Total Funds Approved	\$8,633
Total Funds Expended	\$4,265
Percent of Approved Funds Expended	49.40%

## 3.39 Task Order 92-39

### 3.39.1 Requirement

This task required EER to assemble an IND application for Liposome Encapsulated Repeatless Malaria Vaccine (NS1<sub>g1</sub>RLF). The task included writing the Introductory Statement, editing the Investigator's Brochure, and formatting the table of contents.

### 3.39.2 Accomplishment

EER wrote and finalized the Introductory Statement; edited and finalized the Investigator's Brochure; prepared additional sections of the IND; formatted the table of contents; and assembled and submitted to USAMMDA an IND suitable for submission to the FDA on 19 June 1992. The IND was filed with the FDA and was assigned BB-IND 4613 with the an FDA anniversary date of 29 June 1992.

## 3.39.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	273.5
Total Funds Approved	\$17,726
Total Funds Expended	\$17,591
Percent of Approved Funds Expended	99.24%

## 3.40 Task Order 92-40

### 3.40.1 Requirement

This task required EER to conduct Postmarketing Surveillance of Adverse Drug Events for Injectable Sodium Thiosulfate (NDA #20-166). The task included a monthly literature search of MEDLINE, TOXLINE, AND TOXLIT online databases for abstracts of suspected Adverse Drug Events (ADE); submission of a written review of abstracts of suspected ADE (labelled "serious" and "unexpected"); periodic reporting of adverse drug experience reports at quarterly intervals; and submission of annual reports.

# DRAFT

## 3.40.2 Accomplishment

EER conducted a monthly literature search of the automated databases (MEDLINE, TOXLINE, and TOXLIT); reviewed and analyzed abstracts of materials retrieved; prepared monthly abstract reports describing any suspected adverse drug events (ADE) associated with Injectable Sodium Thiosulfate; and submitted annual reports prior to the FDA anniversary date.

## 3.40.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	596
Total Funds Approved	\$33,742
Total Funds Expended	\$29,059
Percent of Approved Funds Expended	86.12%

## 3.41 Task Order 92-41

### 3.41.1 Requirement

This task required EER to prepare an amendment for BB-IND 3842, Whole Cell B Subunit Cholera Vaccine with Cholera and ETEC indications. The amendment called for clarification, revision, and organization of previously submitted information and inclusion of any new information with regard to the chemistry, manufacturing, and preclinical data. The task included updating the Investigational Plan and responding to questions raised by the FDA.

### 3.41.2 Accomplishment

EER reviewed and organized previously submitted information and prepared an IND amendment for submission to the FDA. A two-volume IND amendment was submitted to USAMMDA on 2 October 1992.

### 3.41.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	425
Total Funds Approved	\$29,265
Total Funds Expended	\$29,799
Percent of Approved Funds Expended	101.82%

# DRAFT

## 3.42 Task Order 92-42

### 3.42.1 Requirement

This task required EER to conduct a cGMP audit of the collection of equine botulinal antitoxin for an F(ab)<sub>2</sub> project contracted by USAMRIID. At the conclusion of the audit, EER was required to review results with key personnel, follow with a written report of audit results, and brief the key operational personnel at USAMRIID of the results after completion of the report.

### 3.42.2 Accomplishment

EER provided regulatory expertise, planned and coordinated the effort, interviewed personnel, observed procedures, critically reviewed relevant SOPs, briefed key USAMRIID personnel of the results of the inspection, provided recommendations for improvements, and prepared and submitted a written report of the inspection to USAMMDA. Results were reviewed with key personnel during a meeting at USAMRIID.

### 3.42.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	59.5
Total Funds Approved	\$5,438
Total Funds Expended	\$5,063
Percent of Approved Funds Expended	93.10%

## 3.43 Task Order 92-043

### 3.43.1 Requirement

This task required EER to assemble an IND application for Dengue 1 16007 PDK-25, 15 and 10. The task included editing the Introductory Statement, formatting the table of contents, and preparing an Investigator's Brochure similar to BB-IND 4394.

### 3.43.2 Accomplishment

EER edited and finalized the Introductory Statement, prepared the Investigator's Brochure and other components of the IND, formatted the table of contents, and prepared and submitted a final IND application for Dengue 1 to USAMMDA on 13 May 1992. The IND was filed with the FDA and was assigned BB-IND 4551 with an FDA anniversary date of 13 May 1992.

# DRAFT

## 3.43.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	68
Total Funds Approved	\$4,814
Total Funds Expended	\$4,500
Percent of Approved Funds Expended	93.47%

## 3.44 Task Order 92-044

### 3.44.1 Requirement

This task required EER to provide USAMRIID assistance in the conduct of a field study of anthrax and botulinum toxoid vaccine. The task included developing case report forms and informed consent forms, finalizing the study protocol, and performing clinical monitoring responsibilities in accordance with the FDA Guidelines for the Monitoring of Clinical Investigators.

### 3.44.2 Accomplishment

EER planned and coordinated the effort for this task; secured the services of Oxford Research (subcontractor) to provide the support required; developed case report forms and informed consent forms; finalized the study protocol; monitored clinical records at Ft. Bragg, North Carolina and Dam Neck and Norfolk, Virginia, and completed data extraction for the control group at Ft. Detrick; gathered and submitted subject accrual data reports; completed case report forms; and prepared site visit reports.

## 3.44.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	698.5
Total Funds Approved	\$99,537
Total Funds Expended	\$61,474
Percent of Approved Funds Expended	61.76%

## 3.45 Task Order 92-045

### 3.45.1 Requirement

This two-phased task required EER's assistance in the establishment and validation of the USAMRIID Good Laboratory and Good Manufacturing Practices (GLP/GMP) program. Phase

# DRAFT

I was to identify and inventory current USAMRIID practices and procedures relating to GLP/GMP and Quality Assurance. This task included providing USAMRIID an assessment of actions required to make the USAMRIID program fully compliant with FDA standards. Phase II was to assist USAMRIID in establishing and validating a fully CFR-compliant GLP/GMP program.

## 3.45.2 Accomplishment

EER assisted USAMRIID in developing policies and procedures for conduct of studies which must meet FDA current Good Laboratory Practices (cGLP). EER provided regulatory expertise, planned and coordinated the effort, conducted meetings, interviewed personnel, observed procedures, critically reviewed relevant SOPs, provided recommendations for improvement, assisted in the preparation of Quality Assurance SOPs, and prepared a GLP Handbook to promulgate the program. The SOP on the preparation, issuing, and control for SOPs, which EER developed for this task, has been integrated into the draft USAMRDC *Handbook for Human Use Studies* as a definitive way to prepare SOPs.

## 3.45.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	2,635
Total Funds Approved	\$157,252
Total Funds Expended	\$157,297
Percent of Approved Funds Expended	100.03%

## 3.46 Task Order 92-046

### 3.46.1 Requirement

This task required EER to assemble and prepare an IND application for the Leishmaniasis skin test antigen and control preparations. The task included writing the Introductory Statement and Investigator's Brochure, formatting the table of contents, and coordinating with WRAIR investigators to complete the IND.

### 3.46.2 Accomplishment

This task was initiated on 13 August 1992. EER participated in all meetings in the planning of the project, offered scientific and regulatory advice, and was consulted numerous times. The task was cancelled by USAMRAA on 15 February 1995. All files and materials received and obtained for this task were placed in the Regulatory Affairs Library.

# DRAFT

## 3.46.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	135
Total Funds Approved	\$16,294
Total Funds Expended	\$13,886
Percent of Approved Funds Expended	85.22%

## 3.47 Task Order 92-047

### 3.47.1 Requirement

This task required development of necessary documentation to support a 510(k) submission to the FDA for the Hand Held Medical X-ray System.

### 3.47.2 Accomplishment

EER provided management support and planned and coordinated the effort; obtained the services of Oxford Research (subcontractor) to provide the support required; critically reviewed documentation prepared by Oxford and provided recommendations for improvements; facilitated submission of the 510(k) application to USAMMDA; and responded to the FDA's request for additional safety and efficacy data. The 510(k) notification to market the device was approved by the FDA on 24 January 1994.

## 3.47.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	387.5
Total Funds Approved	\$24,453
Total Funds Expended	\$22,830
Percent of Approved Funds Expended	93.36%

## 3.48 Task Order 92-048

### 3.48.1 Requirement

This task required EER to convene a panel of experts to produce a collective interpretation of the mutagenic potential of a New Chemical Entity (NCE) and recommend additional research needed to satisfy FDA requirements for adequately determining the mutagenic risk before Phase I clinical trials begin.



# DRAFT

## 3.48.2 Accomplishment

EER selected and assembled a panel of five scientific and regulatory experts to assess the mutagenicity of a new chemical entity (NCE). EER took minutes of meetings and prepared and submitted a report on the panel of experts' analysis of the data provided by USAMMDA, including recommendations for future research of the NCE.

## 3.48.3 Fiscal and Planning Data

Summary of labor and financial data for this task are as follows:

Total EER Manhours Expended	172.5
Total Funds Approved	\$37,646
Total Funds Expended	\$19,677
Percent of Approved Funds Expended	52.27%

## 3.49 Task Order 92-049

### 3.49.1 Requirement

This task required EER to prepare a New Drug Application (NDA) for NAPP (pyridostigmine bromide) for submission to the FDA in accordance with appropriate regulations defined in 21 CFR 314.

### 3.49.2 Accomplishment

EER critically reviewed all materials filed in the Regulatory Affairs Library; submitted a list of deficiencies discovered during the review; coordinated with USAMMDA in obtaining these additional materials; conducted a literature search of the electronic databases for additional information, and retrieved materials that were considered appropriate additional information; secured the service of a toxicologist (to provide critical review information provided by USAMMDA, prepare preclinical data summaries, and advise the EER Task Manager of any deficiencies that would make the application incomplete) and a biostatistician (to conduct analyses of pharmacokinetic and pharmacodynamics parameters for plasma pyridostigmine levels and cholinesterase levels to supplement a draft clinical report); prepared a pre-NDA briefing package for submission to the FDA prior to a pre-NDA meeting with the FDA; attended coordination meetings with USAMMDA and the FDA; took minutes of the meetings; and prepared and submitted an 81-volume NDA application to the FDA on 7 March 1994.

# DRAFT

## 3.49.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	8,871
Total Funds Approved	\$677,766
Total Funds Expended	\$642,058
Percent of Approved Funds Expended	94.73%

## 3.50 Task Order 93-050

### 3.50.1 Requirement

This task required EER to assemble and prepare an IND application for Dengue-1 (16007) PDK-13 and Dengue-4 (1036) PDK-48.

### 3.50.2 Accomplishment

This task was initiated on 9 December 1992. EER critically reviewed all information provided by the Product Manager, prepared working drafts of the INDs, and provided an assessment of materials needed to complete preparation of the IND. The task was cancelled by USAMRAA on 19 October 1994 due to problems in obtaining manufacturing information from Thailand.

## 3.50.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	328
Total Funds Approved	\$32,297
Total Funds Expended	\$29,951
Percent of Approved Funds Expended	92.73%

## 3.51 Task Order 93-051

### 3.51.1 Requirement

This task required EER to prepare an IND application for Topical Skin Protectant (TSP). The task included close coordination with the USAMMDA Product Manager due to influx of data from different sources.

# DRAFT

## 3.51.2 Accomplishment

EER gathered and critically reviewed and analyzed data obtained from the Product Manager; attended coordination meetings with the USAMMDA Product Manager; took meeting minutes; and prepared and assembled an IND suitable for submission to the FDA. A final IND was submitted to USAMMDA on 14 December 1994 and filed with the FDA. It was assigned IND #46,876 with an FDA anniversary date of 16 December 1994.

## 3.51.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	1,736
Total Funds Approved	\$94,598
Total Funds Expended	\$94,780
Percent of Approved Funds Expended	100.19%

## 3.52 Task Order 93-052

### 3.52.1 Requirement

This task required EER to assemble a partially prepared IND, review and prepare an IND for Hantaan M-S (Vaccinia Virus vectored) Vaccine (TSI-GSD 264) suitable for submission to the FDA.

### 3.52.2 Accomplishment

EER prepared and submitted to USAMMDA on 25 June 1993 a final IND application for Hantaan M-S vaccine. The IND was filed with the FDA and was assigned BB-IND 5166 with an FDA anniversary date of 28 June 1993.

### 3.52.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	215.5
Total Funds Approved	\$18,607
Total Funds Expended	\$14,968
Percent of Approved Funds Expended	80.44%

# DRAFT

## 3.53 Task Order 93-053

### 3.53.1 Requirement

This task required EER to assemble and prepare an amendment to the manufacturing section of BB-IND 3723, *Clostridium botulinum* Toxoid Pentavalent Vaccine.

### 3.53.2 Accomplishment

This task was initiated on 8 November 1993 and was cancelled by USAMRAA on 13 July 1995. Manufacturing information for Botulinum E Toxoid was organized to be included in a new formulation of the Pentavalent Vaccine. EER provided USAMMDA all files and materials relating to this task order. The material was organized as the manufacturing section of an IND. An identical file was also filed in the Regulatory Affairs Library.

### 3.53.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	66.5
Total Funds Approved	\$12,116
Total Funds Expended	\$9,317
Percent of Approved Funds Expended	76.90%

## 3.54 Task Order 94-54

### 3.54.1 Requirement

This task required EER to prepare an IND application for Nerve Agent Antidote System (NAAS), HI-6, for submission to the FDA in accordance with 21 CFR 312 and FDA Guidelines on preparation for INDs.

### 3.54.2 Accomplishment

This task was initiated on 18 November 1993 and was cancelled by USAMRAA on 24 February 1995. Prior to the cancellation of the task, EER collected, organized and analyzed extensive materials; prepared and submitted a list of deficiencies in data collected; conducted a literature search of electronic databases for additional information and retrieved materials that were considered appropriate additional information; attended and participated in coordination meetings; and took minutes of the meetings. An unedited working draft of the toxicology section of the HI-6 IND was provided to USAMMDA on 20 February together with an IBM-compatible diskette copy of the draft report.

# DRAFT

## 3.54.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	1,240.5
Total Funds Approved	\$78,983
Total Funds Expended	\$78,571
Percent of Approved Funds Expended	99.48%

## 3.55 Task Order 94-055

### 3.55.1 Requirement

This task required EER to assemble and prepare an IND application for *E. coli* Heat-Labile Toxin to be used as an oral adjuvant.

### 3.55.2 Accomplishment

EER assembled and prepared an IND suitable for submission to the FDA. A final IND was submitted to USAMMDA on 10 May 1994 including an IBM-compatible diskette copy of the IND. The IND was filed with the FDA and was assigned BB-IND 5166 with an FDA anniversary date of 12 May 1994.

## 3.55.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	274.5
Total Funds Approved	\$24,392
Total Funds Expended	\$22,316
Percent of Approved Funds Expended	91.49%

## 3.56 Task Order 94-056

### 3.56.1 Requirement

This task required EER to prepare a Product License Application (PLA) and an Establishment License Application (ELA) for Tularemia Live Vaccine for submission to the Food and Drug Administration in accordance with appropriate regulations defined in 21 CFR 600 and Sections 351 and 352 of the Public Health Service Act.

# DRAFT

## 3.56.2 Accomplishment

EER copied, collected, and critically reviewed all materials relating to this task; provided USAMMDA a list of deficiencies discovered during the review; attended meetings at USAMMDA to coordinate the progress of the task; provided regulatory expertise; coordinated with the Product Manager in resolving issues; prepared and submitted a pre-PLA meeting plan; prepared and submitted to USAMMDA a pre-PLA read-ahead package; and acquired the services of an expert consultant, Dr. Henry Eigelsbach, to assist in the identification and collection of supporting clinical records at USAMRIID and to provide critical review of documents written and generated by EER personnel. Additionally, Dr. Chaparas travelled to The Salk Institute to gather manufacturing information for the ELA. EER prepared and submitted to USAMMDA on 23 June 1995 a seven-volume working draft of the PLA and a five-volume working draft of the ELA for review; and met with USAMMDA Product Manager, COR, and USAMMDA key personnel to discuss Government comments on the draft PLA and ELA. Finalization of both applications will be completed under Contract No. DAMD17-95-C-5087, Task Order 95-007.

## 3.56.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	1,999
Total Funds Approved	\$192,109
Total Funds Expended	\$147,466
Percent of Approved Funds Expended	76.76%

## 3.57 Task Order 94-057

### 3.57.1 Requirement

This task required EER to provide a regulatory affairs post-submission support to USAMMDA to finalize and submit an update (revision) to the PB NDA and to assist in responding to FDA requirements during approval of the PB NDA. It is estimated that support will be required for approximately 18 months.

### 3.57.2 Accomplishment

EER conducted a monthly literature search of the electronic databases (MEDLINE, TOXLINE, and TOXLIT) for publications concerning PB; met with USAMMDA key personnel to discuss preparation of one-time PB NDA update and future requirements; reviewed all narrative volumes of the previously submitted NDA including Battelle's Final Report on Task 92-30; coordinated with USAMRICD in the preparation of a "brief" (precis) to be integrated in the update; and prepared and submitted on 30 June 1995 a working draft of the one-time update

# DRAFT

for review. Preparation of the final update is in progress. This task will be completed under Contract No. DAMD17-95-C-5087, Task Order No. 95-006.

## 3.57.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	2,299.5
Total Funds Approved	\$182,938
Total Funds Expended	\$142,617
Percent of Approved Funds Expended	77.96%

## 3.58 Task Order 94-058

### 3.58.1 Requirement

This task required EER to conduct a mock cGMP inspection of the Botulinum F (A-E) manufacturing facility of the Centre for Applied Microbiology and Research at Porton Down, England. The task included issuing a Form FDA 482 during the in-brief and a Form FDA 483 during the out-brief to the responsible head or designated person; advising the staff on preparation for actual FDA inspection, including QA/QC aspects and relevant legal rights of the facility during the conduct of similar inspection; and providing a written report on the findings to include any corrective action necessary and giving an oral briefing with the appropriate biologics product manager and other USAMMDA personnel, as required.

### 3.58.2 Accomplishment

EER developed and secured USAMMDA's approval of an implementation plan for conduct of the mock GMP inspection; Dr. Chaparas travelled to Porton Down, England and conducted the inspection during the period 20-26 August 1994 with LTC Burman of USAMMDA. EER prepared and submitted a final inspection report to USAMMDA on 24 October 1994.

### 3.58.3 Fiscal and Financial Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	105.5
Total Funds Approved	\$12,303
Total Funds Expended	\$12,096
Percent of Approved Funds Expended	98.32%

# DRAFT

## 3.59 Task Order 94-059

### 3.59.1 Requirement

This task required EER to assess the adequacy of currently available data for preparation of a PLA and an ELA for Argentine Hemorrhagic Fever (AHF) Vaccine. The assessment will be delivered to USAMMDA in the form of a pre-PLA information package.

### 3.59.2 Accomplishment

This task was initiated on 31 August 1994. EER critically reviewed all documentation provided for this task. EER prepared and submitted to USAMMDA a pre-PLA read ahead package on 24 January 1994 for review. This task was cancelled by USAMRAA on 1 February 1995.

### 3.59.3 Fiscal and Planning Data

Labor and financial data for this task are summarized below.

Total EER Manhours Expended	557.5
Total Funds Approved	\$50,000
Total Funds Expended	\$43,861
Percent of Approved Funds Expended	87.72%



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## 4.0 SUMMARIZED WORK AND FISCAL DATA

At contract completion (31 July 1995) EER and associated subcontractors and consultants had provided 60,434\* manhours of labor in support of the Regulatory Affairs contract (DAMD17-89-C-9179). Attachment 3 summarizes labor provided by labor category for each of the 59 tasks assigned. Figure 4.0-1 provides a fiscal analysis of the contract execution indicating that 87.10% of the planned funds were expended. Attachment 4 provides cost totals for each task, by element of expense, and Attachment 5 summarizes funds negotiated to include modifications, cost incurred, and percentage of planned funds expended by task.

\* Excluding 3M Pharmaceuticals' manhours.

# **DAMD17-89-C-9179** **FISCAL ANALYSIS** **AS OF 28 JULY 1995**

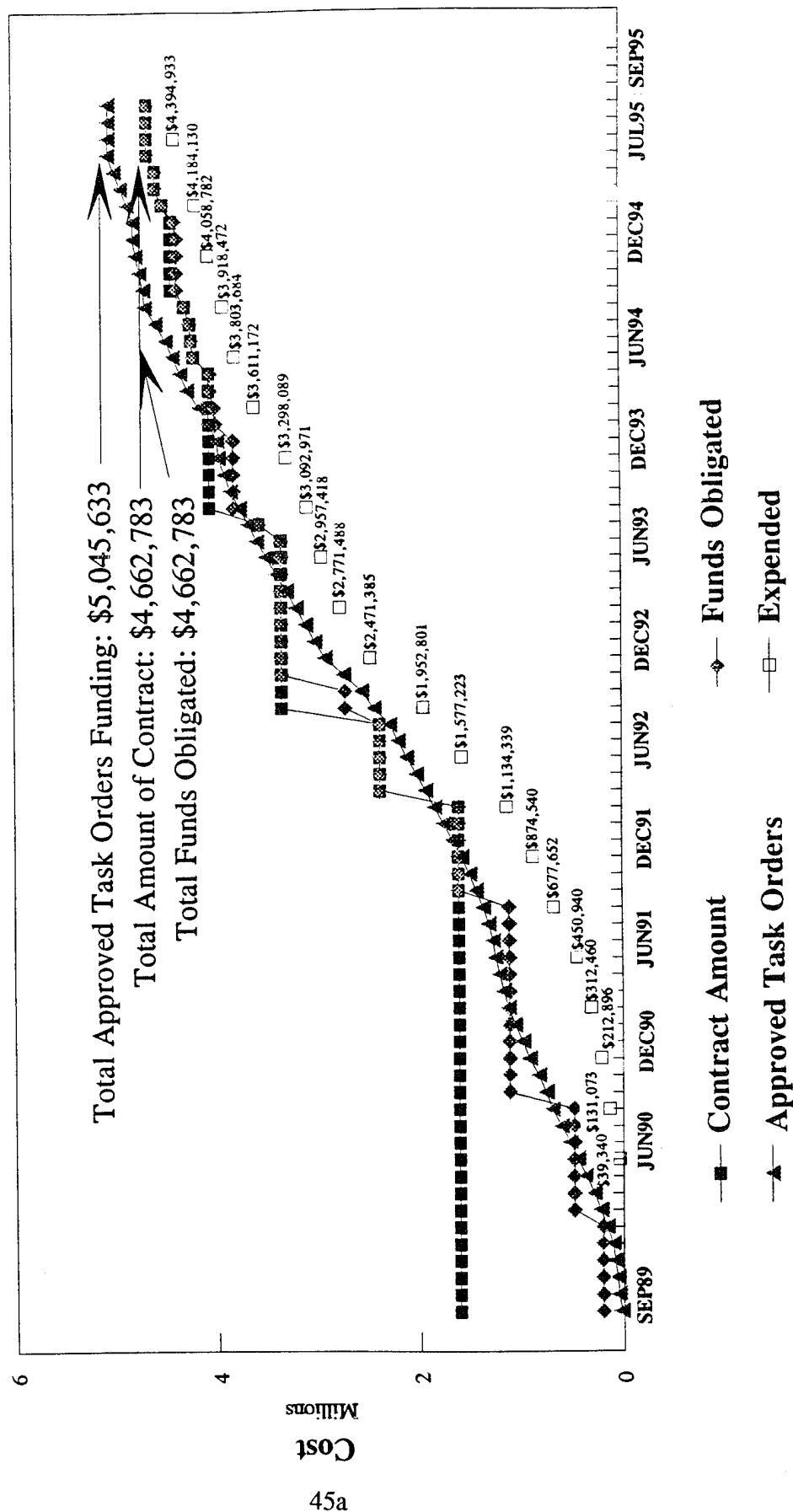


Figure 4.0-1 Provides A Fiscal Analysis of the Contract

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## 5.0 PROBLEMS AND RESOLUTIONS

During execution of this contract a number of technical problems arose which required management action to resolve. Figure 5.0-1 provides a summary of problems experienced and EER Systems actions taken to mitigate these problems.

PROBLEMS EXPERIENCED	MITIGATING EER ACTIONS
<ul style="list-style-type: none"><li>• Quality Control of Final Report</li></ul>	<ul style="list-style-type: none"><li>• Program Adequate Review Time; Insist on Following QA/QC Procedures</li></ul>
<ul style="list-style-type: none"><li>• Incomplete Information to Complete Task</li></ul>	<ul style="list-style-type: none"><li>• Have Open/Frequent Communications Between EER Principal Scientist and Project/Product Managers</li><li>• Assign Task Order Early</li><li>• Encourage Regulatory Review at Milestone 1 Decision</li></ul>
<ul style="list-style-type: none"><li>• Conflicting Opinions Concerning Regulatory Requirements</li></ul>	<ul style="list-style-type: none"><li>• Identify Differences Early; Obtain Expert Opinion if Requested; Support USAMMDA Decision</li></ul>
<ul style="list-style-type: none"><li>• Incomplete Data in Database</li></ul>	<ul style="list-style-type: none"><li>• Frequent Interface with Product Manager to Encourage Filing of Information in Database</li><li>• Planned Visit of Technical Writer with Product Manager to Review Available Data Before Draft Prepared</li></ul>
<ul style="list-style-type: none"><li>• Retrospective Regulatory Strategy Development and Data Collection</li></ul>	<ul style="list-style-type: none"><li>• Work with USAMMDA Project Managers to Develop Clear Regulatory Strategy Early to Guide Study Designs and Timely Data Collection</li></ul>

**Figure 5.0-1: Problems Which Surfaced Were Resolved or Their Impacts Mitigated.**

Schedule control to ensure that adequate time is available for quality control of the final deliverable was a recurring problem. This problem was more pronounced with larger, more complex documentation requirements. Several different methods were employed by EER to improve the quality of the final product with varying success. The most critical factors to improving quality control appear to be allowing adequate time for quality control and being disciplined in following established quality control procedures.

# DRAFT

Incomplete data at the time of task assignment was frequently a problem. To avoid this problem, we encouraged early assignment of tasks so that the Principal Scientist and USAMMDA Product Managers could make an early joint assessment of available and still-needed data. This early assignment also helped ensure a complete understanding of regulatory requirements. Additionally, our open communication management process encouraged frequent discussions between our personnel and USAMMDA personnel, helping clarify requirements. Finally, we strongly encouraged that USAMMDA invite EER regulatory advice during the decisionmaking process for moving products from basic research to advanced development (Milestone 1). This step helped identify regulatory shortcomings before a product was accepted for the development phase. The database system also helped identify completeness of available data.

Conflicting opinions concerning regulatory requirements periodically arose. We immediately brought the issues to USAMMDA's attention and provided our best advice. With USAMMDA's concurrence we sought an opinion from the FDA to resolve the issue.

Not all USAMMDA Product Managers regularly filed data in the EER-maintained Regulatory database. As a result the database was sometimes incomplete for supporting documentation development. This situation contributed to a delay in task completion. We reduced the impact of this problem by encouraging, at every opportunity, Product Managers to file new material in the database as received. During development of IND Annual Reports, EER personnel reviewed and copied Product Manager files for inclusion in the database.

For a variety of reasons a regulatory strategy for licensure approval of Army products was often not developed until late in the development lifecycle. Consequently, much of the supporting research was developed without a clear-cut focus on regulatory requirements for approval. This resulted in delays in data collection and/or requirements for the support contractor to retrospectively fit available data to regulatory requirements in a less than optimal manner. This situation is not only inefficient by often resulted in marginal satisfaction of FDA requirements. We continually encouraged USAMMDA to seek early advice to develop a clear regulatory strategy for product development.

The problems cited herein were resolved or their impacts mitigated through the dedicated efforts of many government and contractor personnel.

# DRAFT

## 6.0 CONCLUSIONS

The objective of this procurement to facilitate the timely and efficient execution of the U.S. Army medical materiel development program by providing a mechanism for preparing and assembling both generic and product-specific FDA-related documentation, as well as a data management system for managing associated regulatory documentation was met.

**DRAFT**

**ATTACHMENT 1**

**LIST OF CONTRACT MODIFICATIONS**

# ATTACHMENT 1

## LIST OF CONTRACT MODIFICATIONS

Contract/ Amendments/ Modifications	Contract Value (incl. fixed fee)	Funds Provided (incl. fixed fee)	Date Signed	Description
DAMD17-89-C-9179	\$1,608,535	\$198,149	9/27/89	Original Contract
P90001	\$1,608,535	\$198,149	9/27/89	Par. H.8. on page 24 of the basic contract is deleted and replaced. (Representations and Certifications)
P00002	\$1,608,535	\$198,149	03/01/90	Mutual Agreement- Contractor's name changed from Engineering and Economics Research, Inc. to EER Systems. Project Manager is changed from Ben P. Daughtry to Frank Bettinger.
P00003	\$1,608,535	\$198,149	04/10/90	Mutual Agreement- Par. F.3.1.1 on page 11 of the contract is changed. A requirement for quarterly reports is added to Section F of the contract schedule. Quarterly reports are due within <b>15 calendar days after the end of the quarter.</b>
P00004	\$1,608,535	\$483,494	03/30/90	Contract Clause H.9. Incremental funding - additional \$285,345 (including fixed fee of \$20,644)
P00005	\$1,608,535	\$483,494	04/27/90	Mutual Agreement- Principal Scientist, Biologics is changed from John J. Gavin, Ph.D. to Harold Baer, Ph.D. and changed in accounting appropriation data in item 2, page 2 of Mod No. 4.
P00006	\$1,608,535	\$483,494	07/09/90	FAR Clause 52.245-5, government property. Government property previously accountable under Contract No. DAMD17-86-C-6189 is transferred to this contract.

# ATTACHMENT 1

## LIST OF CONTRACT MODIFICATIONS

Contract/ Amendments/ Modifications	Contract Value (incl. fixed fee)	Funds Provided (incl. fixed fee)	Date Signed	Description
P00007	\$1,608,535	\$483,494	07/31/90	Mutual Agreement-- Far 52.243-2, Changes--Cost Reimbursement. Par. H.14.j(1) on page 28 of the contract is deleted and replaced. (Task Orders Operating Procedures)
P00008	\$1,608,535	\$1,114,683	11/29/90	Contract Clause H.9. Incremental funding - additional \$631,189 (including fixed fee of \$45,667)
P00009	\$1,608,535	\$1,114,683	01/09/91	Page 13, Paragraph F.5.1. of Contract Schedule. EER Project Manager is changed from Frank Bettinger to Carl R. Morin, Jr. Level of effort for PM is unchanged; 1,996 total hours proposed over the life of the 3-year contract including the two one-year options.
P10010	\$1,608,535	\$1,114,683	06/07/91	Sec. F.5, Key Personnel Principal Scientist, Biologics is changed from Harold Baer, Ph.D. to Sotiros Chaparas, Ph.D.
P20011	\$1,608,535	\$1,608,535	10/28/91	Contract Clause H.9. Incremental funding - additional \$493,852 (including fixed fee of \$35,731)
P20012	\$1,608,535	\$1,608,535	12/17/91 (Received)	Contract is modified to incorporate EER's revised Small Business and Small Disadvantaged Business Subcontracting Plan into the contract by reference.
P20013	\$2,385,871	\$2,385,871	03/30/92 (Received)	Additional funding: \$777,336 (includes \$57,117 fixed fee) added to the contract. (TO# 91-25 Mod 1, 2 and 9235)



# ATTACHMENT 1

## LIST OF CONTRACT MODIFICATIONS

Contract/ Amendments/ Modifications	Contract Value (incl. fixed fee)	Funds Provided (incl. fixed fee)	Date Signed	Description
P20014	\$2,385,871	\$2,385,871	07/16/92 (Received)	1) Sec. F.5.1, Key Personnel Principal Scientist, Pharmaceuticals, is changed from Dr. Art Horowitz to Dr. Bob West. 2) Option to Extend the Term of the Contract is incorporated by reference into Section I. of the contract schedule.
P20015	\$2,485,408	\$2,485,408	07/16/92 (Received)	Additional funding: \$99,537 (includes \$7,182 fixed fee) added to the contract. (TO# 9244)
P20016	\$2,606,804	\$2,606,804	8/25/92 (Received)	Additional funding: \$121,396 (includes \$8,759 fixed fee) added to the contract. (TO# 9125 Mod 3, 9245, and 9246)
P20017	\$3,234,801	\$2,606,804	09/28/92 (Received)	A. \$627,997 provided for exercising Option to Extend the Term of the contract. B. Contract extended to 28 Sept. 1993. C. Accounting and appropriation is subject to Congress enacting appropriation.
P20018	\$3,354,617	\$2,726,620	9/29/92	Additional funding: \$119,816 (including fixed fee of \$8,645) added to the contract for continued performance of task order. (TO# 9245)
P30019	\$3,354,617	\$3,354,617	11/17/92	The \$627,997 in FY93 dollars were released. Mod No. P30019 deletes "Subject to Congress Enacting Appropriations" on Mod No. P20017.
P30020	\$3,354,617	\$3,354,617	2/5/93	Accounting appropriation data shown in proceeding modifications were changed.
P30021	\$3,502,391	\$3,502,391	8/24/93	Additional funding - \$147,774 including fixed fee of \$11,577

# ATTACHMENT 1

## LIST OF CONTRACT MODIFICATIONS

Contract/ Amendments/ Modifications	Contract Value (incl. fixed fee)	Funds Provided (incl. fixed fee)	Date Signed	Description
P30022	\$3,570,391	\$3,570,391	8/24/93	Additional funding - \$68,000 including fixed fee of \$5,327
P30023	\$4,057,968	\$3,817,988	09/10/93	A. Option Two in the amt of \$487,577 including fixed fee is exercised in accordance with Par H.12. "Option to Extend the Term of the Contract". (Amount was added to the total value of the contract subject to Congress Enacting Appropriations) B. Provide additional funds of \$247,597 including fixed fee.
P30024	\$4,057,968	\$3,817,988	09/21/93	Changed in accounting and appropriation data.
P40025	\$4,057,968	\$3,817,988	10/14/93	Accounting and appropriation data shown on Mod P30023 is changed and deletes "Subject to Congress Enacting Appropriations"
P40026	\$4,057,968	\$3,817,988	11/23/93	Accounting and appropriation data shown on Mod P30023 is changed and deletes "Subject to Congress Enacting Appropriations"
P40027	\$4,057,968	\$3,817,988	12/7/93	Accounting and appropriation data shown on Mod P40025 is changed.
P40028	\$4,057,968	\$3,992,378	02/22/94	Incremental funding - \$174,390 including fixed fee of \$11,769)
P40029	\$4,057,968	\$3,992,378	03/08/94	Government furnished property identified in Mod P00006, Government Tag No. 0008 (tape drive) deleted from the contract schedule, and 2 Government furnished property, Tag No. 0016 and 0017 (tape drives) are added to the contract schedule.
P40030	\$4,057,968	\$4,002,549	03/08/94	Incremental funding in the amount of \$10,171 (incl. fixed fee of \$683)
P40031	\$4,057,968	\$4,040,665	04/20/94	Incremental funding in the amount of \$38,116 (incl. fixed fee of \$2,744)

# ATTACHMENT 1

## LIST OF CONTRACT MODIFICATIONS

Contract/ Amendments/ Modifications	Contract Value (incl. fixed fee)	Funds Provided (incl. fixed fee)	Date Signed	Description
P40032	\$4,204,097	\$4,204,097	05/27/94	Incremental funding in the amount of \$17,303 and additional funding in the amount of \$146,129 (incl. fixed fee of \$11,713)
P40033	\$4,227,847	\$4,227,847	07/28/94	Additional funding - \$23,750 including fixed fee of \$1,702) (Task #93-50 Mod 1 and 93-51 Mod 1)
P40034	\$4,240,150	\$4,240,150	08/17/94	Additional funding - \$12,303 including fixed fee of \$875) (Task #94-58)
P40035	\$4,295,150	\$4,295,150	09/07/94	Additional funding - \$55,000 including fixed fee of \$3,912) (Task #94-55)
P40036	\$4,428,130	\$4,372,775	09/26/94	Extension of contract performance for all active tasks from 29 Sept 1994 to 30 March 1995, 1 April 1995 to 15 June 1995 for preparation and submission of the final report, and additional funding in the amount of \$77,625 (incl. fixed fee of \$5,522) added to the contract schedule and the remaining \$55,355 funds will be provided on or about 1 November 1994.
P50037	\$4,428,130	\$4,372,775	10/20/94	Accounting and appropriation data totalling \$71,875 (incl. fixed fee of \$5,113) identified in Mod P40036 no longer subject to Congress approval.
P50038	\$4,428,130	\$4,393,722	02/06/95	Incremental funding in the amount of \$20,947 (incl. fixed fee of \$1,356)
P50039	\$4,514,555	\$4,514,555	03/14/95	Incremental funding in the amount of \$34,408 (incl. fixed fee of \$2,228) and additional funding in the amount of \$86,425 (incl. fixed fee of \$5,596)

# ATTACHMENT 1

## LIST OF CONTRACT MODIFICATIONS

Contract/ Amendments/ Modifications	Contract Value (incl. fixed fee)	Funds Provided (incl. fixed fee)	Date Signed	Description
P50040	\$4,582,198	\$4,582,198	03/30/95	Additional funding in the amount of \$67,643 (incl. fixed fee of \$4,812) in support of Tasks 89-01, 89-02, 90-03, 91-22, and 92-40. Tasks 93-53, 94-56, and 94-57 period of performance extended. Contract period of performance also changed from 29 September 1989 - 15 June 1995 to 29 September 1989 - 15 September 1995, wherein 1-31 July 1995 is reserved for final report preparation and submission, 1-31 August 1995 is reserved for government's review and 1-15 September 1995 is reserved for contractor revisions and resubmission.
P5001	\$4,662,783	\$4,662,783		Additional funding in the amount of \$80,585 (incl. fixed fee of \$5,732) added to the contract schedule to support Task Order Nos. 94-56 and 94-57 through 30 June 1995.
P50042	\$4,662,783	\$4,662,783		Period of Performance Extended for Task Nos. 89-01, 89-02, 90-03, 91-22, 92-44, 94-56, and 94-57 extended through 31 July 1995. 1-31 August 1995 is reserved for final report preparation and submission, 1-30 September 1995 is reserved for Government's review, and 1-15 October is reserved for contractor revisions and resubmission.

**DRAFT**

**ATTACHMENT 2**

**DETAILED LISTING OF TASK ORDERS WITH  
ASSOCIATED MODIFICATIONS AND APPROVED FUNDING**

# ATTACHMENT 2

## DETAILED LISTING OF TASK ORDERS WITH ASSOCIATED MODIFICATIONS AND APPROVED FUNDING

TASK NO.	PERIOD OF PERFORMANCE	DATE TASK APPROVED	AMOUNT OF ORDER	FIXED FEE	TOTAL	CUM TOTAL	DESCRIPTION	STATUS
8901 8901 Mod 1 8901 Mod 2 8901 Mod 3 8901 Mod 4	29 Sep 1989 - 30 Sep 1992 29 Sep 1992 - 28 Sep 1993 29 Sep 1993 - 28 Sep 1994 29 Sep 1994 - 30 Mar 1995 31 Mar 1995 - 30 Jun 1995	30 Mar 1990 18 Nov 1992 14 Oct 1993 19 Oct 1994 21 Apr 1995	\$360,017 \$107,263 \$110,174 \$48,332 \$28,495 \$654,281	\$27,392 \$8,322 \$8,770 \$3,701 \$2,182 \$50,367	\$387,409 \$115,585 \$118,944 \$52,033 \$30,677 \$704,648		TEP Approved Mod 1 received on 11/18/92 Mod 2 approved by USAMRAA on 10/14/93 Mod 3 approved by USAMRAA on 10/19/94 Mod 4 approved by USAMRAA on 04/21/95	IN-PROGRESS
8902 8902 Mod 1 8902 Mod 2 8902 Mod 3 8902 Mod 4	29 Sep 1989 - 28 Sep 1992 29 Sep 1992 - 28 Sep 1993 29 Sep 1993 - 28 Sep 1994 29 Sep 1994 - 30 Mar 1995 31 Mar 1995 - 30 Jun 1995	6 Oct 1989 17 Nov 1992 14 Oct 1993 19 Oct 1994 21 Apr 1995	\$105,248 \$31,471 \$33,059 \$21,487 \$11,354 \$202,619	\$8,299 \$2,442 \$2,632 \$1,646 \$870 \$15,889	\$113,547 \$33,913 \$35,691 \$23,133 \$12,224 \$218,508		TEP Approved Mod 1 received on 11/18/92 Mod 2 approved by USAMRAA on 10/14/93 Mod 3 approved by USAMRAA on 10/19/94 Mod 4 approved by USAMRAA on 04/21/95	COMPLETED
9003 9003 Mod 1 9003 Mod 2 9003 Mod 3 9003 Mod 4 9003 Mod 5	1 Feb 1990 - 30 Sep 1992 1 Oct 1992 - 30 Sep 1993 1 Oct 1992 - 30 Sep 1993 1 Oct 1993 - 30 Sep 1994 1 Oct 1994 - 30 Mar 1995 31 Mar 1995 - 30 Jun 1995	14 Mar 1990 8 Feb 1993 17 Feb 1993 14 Oct 1993 19 Oct 1994 21 Apr 1995	\$303,593 \$0 (\$129,032) \$48,347 \$21,960 \$15,229 \$260,097	\$23,750 \$0 (\$10,968) \$3,848 \$1,682 \$1,166 \$19,478	\$327,343 \$0 (\$140,000) \$52,195 \$23,642 \$16,395 \$279,575	\$1,202,731	TEP Revised Mod 1 submitted to USAMRAA on 10/22/92 Task order funding decreased by \$140K Mod 3 approved by USAMRAA on 10/14/93 Mod 4 approved by USAMRAA on 10/19/94 Mod 5 approved by USAMRAA on 04/21/95	COMPLETED
9004 9004 Mod 1 9004 Mod 2	15 May 1990 - 15 Oct 1991 15 May 1990 - 15 Oct 1991 15 May 1990 - 15 Oct 1991	2 Jul 1990 12 Apr 1991 19 Apr 1991	\$193,972 \$0 \$0 \$193,972	\$13,351 \$0 \$0 \$13,351	\$207,323 \$0 \$0 \$207,323	\$1,410,054	TEP 3M to prepare NDA Supplement NDA Supplement submission changed to 09/18/91	COMPLETED
9005 9005 Mod 1 9005 Mod 2	1 May 1990 - 1 May 1991 1 May 1990 - 31 Dec 1991 1 May 1990 - 31 Dec 1991	3 May 1990 9 May 1991 1 May 1992	\$37,994 \$0 \$0 \$37,994	\$2,978 \$0 \$0 \$2,978	\$40,972 \$0 \$0 \$40,972	\$1,451,026	TEP Period of performance extended Task cancelled - preclinical data insufficient for IND submission	CANCELLED
9006 9006 Mod 1 9006 Mod 2	1 May 1990 - 1 May 1991 1 May 1990 - 31 Dec 1991 1 May 1990 - 31 Dec 1991	27 Apr 1990 9 May 1991 3 Jan 1992	\$37,994 \$0 \$0 \$37,994	\$2,978 \$0 \$0 \$2,978	\$40,972 \$0 \$0 \$40,972	\$1,491,998	TEP Period of performance extended Mod to closeout task	COMPLETED
9007	1 Jul 1990 - 30 Sept 1990	2 Jul 1990	\$5,796	\$454	\$6,250	\$1,498,248	TEP	COMPLETED
PAGE TOTAL			\$1,392,753	\$105,495	\$1,498,248			

TASK NO.	PERIOD OF PERFORMANCE	DATE TASK APPROVED	AMOUNT OF ORDER	FIXED FEE	TOTAL	CUM TOTAL	DESCRIPTION	STATUS
9008 9008 Mod 1 9008 Mod 2	1 Aug 1990 – 1 Dec 1990 15 Nov 1990 – 30 Jan 1991 15 Nov 1990 – 30 Jan 1991	10 Aug 1990 12 Dec 1990 29 Apr 1991	\$6,198 \$16,084 \$1,638 \$23,920	\$485 \$1,258 \$128 \$1,871	\$6,683 \$17,342 \$1,766 \$25,791	\$1,524,039	TEP Additional funding Additional funding	COMPLETED
9009 9009 Mod 1 9009 Mod 2	1 Sep 1990 – 31 Dec 1990 1 Sep 1990 – 31 Dec 1990 1 Sep 1990 – 30 June 1991	24 Aug 1990 12 Sep 1990 9 May 1991	\$29,988 \$2,452 \$0 \$32,440	\$2,346 \$192 \$0 \$2,538	\$32,334 \$2,644 \$0 \$34,978	\$1,559,017	TEP Additional funding Period of performance extended	COMPLETED
9010	15 Sep 1990 – 15 Jan 1991	12 Sep 1991	\$30,014	\$2,348	\$32,362	\$1,591,379	TEP	COMPLETED
9011 9011 Mod 1	1 Oct 1990 – 30 Dec 1990 1 Oct 1990 – 30 Dec 1990	26 Oct 1990 26 Dec 1990	\$14,883 \$0 \$14,883	\$1,164 \$0 \$1,164	\$16,047 \$0 \$16,047	\$1,607,426	TEP Cancelled – 12/26/90; Smith Kline Beecham to do IND	CANCELLED
9012 9012 Mod 1 9012 Mod 2 9012 Mod 3 9012 Mod 4	1 Oct 1990 – 30 Dec 1990 1 Oct 1990 – 31 Dec 1991 1 Oct 1992 – 30 Apr 1992 1 Oct 1990 – 30 Nov 1992 1 Oct 1990 – 31 Jan 1993	26 Dec 1990 9 May 1991 7 May 1992 26 Oct 1992 12 Jan 1993	\$16,988 \$0 \$8,698 \$8,097 \$6,638 \$40,421	\$1,329 \$0 \$679 \$628 \$515 \$3,151	\$18,317 \$0 \$9,377 \$8,725 \$7,153 \$43,572	\$1,650,998	TEP Period of performance extended Additional funding Telephonic approval received on 10/26/92 Mod 4 approved on 01/12/93	COMPLETED
9113 9113 Mod 1 9113 Mod 2 9113 Mod 3 9113 Mod 4	15 Nov 1990 – 1 Mar 1991 15 Nov 1990 – 1 Jul 1991 15 Nov 1990 – 30 Aug 1991 15 Nov 1990 – 31 Oct 1991 15 Nov 1990 – 31 Oct 1991	12 Dec 1990 14 May 1991 25 Jul 1991 29 Nov 1991 29 Nov 1991	\$18,835 \$3,281 \$5,741 \$0 \$2,363 \$30,220	\$1,474 \$257 \$449 \$0 \$185 \$2,365	\$20,309 \$3,538 \$6,190 \$0 \$2,548 \$32,585	\$1,683,583	TEP Additional funding Additional funding Mod 3 to respond to IND deficiency letter from FDA Additional funding	COMPLETED
	PAGE TOTAL		\$171,898	\$13,437	\$185,335			

TASK NO.	PERIOD OF PERFORMANCE	DATE TASK APPROVED	AMOUNT OF ORDER	FIXED FEE	TOTAL	CUM TOTAL	DESCRIPTION	STATUS
9114 9114 Mod 1 9114 Mod 2	15 Nov 1990 - 1 Mar 1991 15 Nov 1990 - 31 Jul 1991 15 Nov 1990 - 31 Oct 1991	29 Nov 1990 9 May 1991 11 Sep 1991	\$17,275 \$0 \$4,449 \$21,724	\$1,352 \$0 \$348 \$1,700	\$18,627 \$0 \$4,797 \$23,424	\$1,707,007	TEP Period of performance extended Additional funding & period of performance extended	COMPLETED
9115 9115 Mod 1 9115 Mod 2 9115 Mod 3	15 Nov 1990 - 1 Mar 1991 15 Nov 1990 - 31 Jul 1991 15 Nov 1990 - 15 Dec 1991	29 Nov 1990 9 May 1991 2 Jan 1992 4 Mar 1993	\$22,180 \$0 \$14,247 \$6,033 \$42,460	\$1,735 \$0 \$1,113 \$468 \$3,316	\$23,915 \$0 \$15,360 \$6,501 \$45,776	\$1,752,783	TEP Period of Performance extended Additional Funding Mod 3 approved on 4 March 1993	COMPLETE
9116 9116 Mod 1 9116 Mod 2	30 Dec 1990 - 1 Mar 1991 30 Dec 1990 - 31 Jul 1991	2 Jan 1991 9 May 1991 31 Jul 1992	\$22,609 \$0 \$0 \$22,609	\$1,769 \$0 \$0 \$1,769	\$24,378 \$0 \$0 \$24,378	\$1,777,161	TEP Period of Performance extended Cancelled - 7/31/92, manufacturer could not meet cGMP requirements	CANCELLED
9117 9117 Mod 1 9117 Mod 2	30 Jan 1991 - 30 June 1991 30 Jan 1991 - 1 Nov 1991 30 Jan 1991 - 30 Dec 1991	5 Feb 1991 11 Sep 1991 20 Nov 1991	\$17,275 \$10,208 \$3,988 \$31,471	\$1,352 \$799 \$311 \$2,462	\$18,627 \$11,007 \$4,299 \$33,933	\$1,811,094	TEP Additional funding & performance period extended Additional funding & performance period extended	COMPLETE
9118	13 Feb 1991 - 1 Apr 1991	20 Mar 1991	\$19,145	\$1,498	\$20,643	\$1,831,737	TEP	COMPLETE
9119	22 Mar 1991 - 15 May 1991	27 Mar 1991	\$15,426	\$1,207	\$16,633	\$1,848,370	TEP	COMPLETE
9120 9120 Mod 1 9120 Mod 2	1 Apr 1991 - 30 Dec 1991 1 Apr 1991 - 30 Dec 1991 1 May 1992	27 Mar 1991 16 May 1991 1 May 1992	\$18,301 \$1,734 \$0 \$20,035	\$1,432 \$136 \$0 \$1,568	\$19,733 \$1,870 \$0 \$21,603	\$1,869,973	TEP Attend meeting at Birmingham, AL Cancelled - 5/7/92, task order no longer needed by USAMMDA	CANCELLED
9121 9121 Mod 1 9121 Mod 2 9121 Mod 3	15 Nov 1990 - 1 Jul 1991 15 Nov 1990 - 30 Aug 1991 15 Nov 1990 - 31 Jan 1992 15 Nov 1990 - 31 Jan 1992	14 May 1991 24 Jul 1991 20 Nov 1991 20 Nov 1991	\$9,524 \$7,071 \$0 \$2,363 \$18,958	\$745 \$553 \$0 \$185 \$1,483	\$10,269 \$7,624 \$0 \$2,548 \$20,441	\$1,890,414	TEP Increased labor, travel, and photocopying To respond to IND deficiency letter of the FDA Additional funding	COMPLETE
PAGE TOTAL			\$191,828	\$15,003	\$206,831			



TASK NO.	PERIOD OF PERFORMANCE	DATE TASK APPROVED	AMOUNT OF ORDER	FIXED FEE	TOTAL	CUM TOTAL	DESCRIPTION	STATUS
9122	1 June 1991 - 28 Sep 1992	12 Jun 1991	\$21,726	\$1,700	\$23,426		TEP	COMPLETED
9122 Mod 1	1 June 1991 - 28 Sep 1992	23 Aug 1991	\$5,483	\$429	\$5,912		Additional funding/requirement	
9122 Mod 2	29 Sep 1992 - 28 Sep 1993	30 Nov 1992	\$16,129	\$1,251	\$17,380		Revised Mod 2 approved by USAMRAA on 11/30/92	
9122 Mod 3	29 Sep 1993 - 28 Sep 1994	28 Oct 1993	\$18,841	\$1,500	\$20,341		Mod 3 approved by USAMRAA on 10/28/93	
9122 Mod 4	29 Sep 1993 - 28 Sep 1994	3 Feb 1994	\$0	\$0	\$0		Mod 4 - changed in task order deliverables (02/03/94)	
9122 Mod 5	29 Sep 1994 - 30 Mar 1995	19 Oct 1994	\$8,957	\$686	\$9,643		Mod 5 approved by USAMRAA on 10/19/94	
9122 Mod 6	31 Mar 1995 - 30 Jun 1995	21 Apr 1995	\$5,144	\$394	\$5,538		Mod 6 approved by USAMRAA on 04/21/95	
			\$76,280	\$5,960	\$82,240	\$1,972,654		
9123	15 Aug 1991 - 31 Jan 1992	5 Sep 1991	\$23,958	\$1,874	\$25,832	\$1,998,486	TEP	COMPLETED
9124	15 Aug 1991 - 29 Feb 1992	5 Sep 1991	\$23,958	\$1,874	\$25,832		TEP	CANCELLED
9124 Mod 1		23 Jul 1992	\$0	\$0	\$0	\$2,024,318	Cancelled - 7/23/92, NIH will assemble IND	
			\$23,958	\$1,874	\$25,832			
9125	27 Aug 1991 - 26 Aug 1993	10 Oct 1991	\$458,619	\$35,297	\$493,916		TEP	INITIAL REQUIREMENT COMPLETED
9125 Mod 1	27 Aug 1991 - 26 Aug 1993	5 Nov 1991	\$9,459	\$728	\$10,187		Additional deliverable, prepare minutes of meetings	
9125 Mod 2	27 Aug 1991 - 26 Aug 1993	18 Dec 1991	\$19,743	\$1,519	\$21,262		ORIC to develop pre-submission PMA Study Plan	
9125 Mod 3	27 Aug 1991 - 26 Aug 1993	26 Aug 1992	\$40,409	\$3,142	\$43,551		Provide additional assistance to Sterimatics	
9125 Mod 4	27 Aug 1991 - 26 Aug 1993	18 Nov 1992	\$108,002	\$8,379	\$116,381		Additional funding, photocopy and assemble IND	
9125 Mod 5	27 Aug 1992 - 26 Apr 1994	17 Mar 1993	\$166,369	\$13,476	\$179,845		Mod 5 approved by USAMRAA on 03/17/93	
9125 Mod 6		14 Jan 1994	(\$100,000)	\$0	(\$100,000)	\$2,789,460	Mod 6 - post-submission support requirement cancelled and \$10K deobligated	
			\$702,601	\$62,541	\$765,142			
9126	1 Oct 1991 - 28 Feb 1992	23 Oct 1991	\$21,557	\$1,684	\$23,241	\$2,812,701	TEP	COMPLETED
9127	15 Oct 1991 - 31 Jan 1992	23 Oct 1991	\$15,291	\$1,196	\$16,487	\$2,829,188	TEP	COMPLETED
9228	01 Nov 1991 - 31 Jan 1992	20 Nov 1991	\$7,540	\$589	\$8,129	\$2,837,317	TEP	COMPLETED
9229	15 Nov 1991 - 15 Feb 1992	29 Nov 1991	\$14,087	\$1,100	\$15,187	\$2,852,504	TEP	COMPLETED
9230	25 Nov 1991 - 31 Jan 1992	5 Dec 1991	\$2,218	\$173	\$2,391		TEP	COMPLETED
9230 Mod 1	25 Nov 1991 - 30 Apr 1992	24 Jan 1992	\$5,026	\$392	\$5,418		Prepare summary for 2 additional surveys	
			\$7,244	\$565	\$7,809	\$2,860,313		
		PAGE TOTAL	\$892,516	\$77,383	\$969,899			

TASK NO.	PERIOD OF PERFORMANCE	DATE TASK APPROVED	AMOUNT OF ORDER	FIXED FEE	TOTAL	CUM TOTAL	DESCRIPTION	STATUS
9231	25 Nov 1991 – 31 Jan 1992	6 Dec 1990	\$8,520	\$665	\$9,185	\$2,869,498	TEP	COMPLETED
9232	15 Dec 1991 – 30 June 1992	8 Jan 1992	\$23,081	\$1,803	\$24,884	\$2,894,382	TEP	COMPLETED
9233	13 Dec 1991 – 29 Feb 1992	8 Jan 1992	\$13,275	\$1,037	\$14,312	\$2,908,694	TEP	COMPLETED
9234 9234 Mod 1	15 Dec 1991 – 31 Mar 1992	8 Jan 1992 2 Apr 1993	\$13,042 \$0 \$13,042	\$1,018 \$0 \$1,018	\$14,060 \$0 \$14,060	\$2,922,754	TEP Task cancelled – 04/2/93	CANCELLED
9235 9235 Mod 1 9235 Mod 2	1 Feb 1992 – 30 Sep 1992	21 Feb 1992 4 Mar 1992 14 May 1992	\$40,046 \$199,581 \$4,989 \$244,616	\$2,289 \$17,675 \$390 \$20,354	\$42,335 \$217,256 \$5,379 \$264,970	\$3,187,724	Funding for Elements E1 and E2 of TEP Remaining TEP funding Develop action plan and brief CG	COMPLETED
9236 9236 Mod 1	1 Mar 1992 – 31 Jul 1992	9 Apr 1992 23 Jul 1992	\$35,588 \$0 \$35,588	\$2,779 \$0 \$2,779	\$38,367 \$0 \$38,367	\$3,226,091	TEP Task cancelled by USAMRAA on 7/24/92. Current formulation of 30 tables, 3x a day unsuitable	CANCELLED
9237	1 Mar 1992 – 30 June 1992	3 Apr 1992	\$8,008	\$625	\$8,633	\$3,234,724	TEP	COMPLETED
9238	1 Mar 1992 – 30 June 1992	3 Apr 1992	\$8,008	\$625	\$8,633	\$3,243,357	TEP	COMPLETED
9239	1 Apr 1992 – 30 June 1992	3 Apr 1992	\$16,442	\$1,284	\$17,726	\$3,261,083	TEP	COMPLETED
9240 9240 Mod 1 9240 Mod 2 9240 Mod 3 9240 Mod 4 9240 Mod 5	1 Apr 1992 – 28 Sep 1992 29 Sep 1992 – 28 Sep 1993 29 Sep 1993 – 28 Sep 1994 29 Sep 1993 – 28 Sep 1994 29 Sep 1994 – 30 Mar 1995 31 Mar 1995 – 30 Jun 1995	14 Apr 1992 9 Dec 1992 28 Oct 1993 3 Feb 1994 19 Oct 1994 21 Apr 1995	\$5,743 \$8,192 \$9,851 \$0 \$4,902 \$2,611 \$31,299	\$449 \$635 \$784 \$0 \$375 \$200 \$2,443	\$6,192 \$8,827 \$10,635 \$0 \$5,277 \$2,811 \$33,742	\$3,294,825	TEP Revised Mod 1 approved on 12/9/92 Mod 2 approved by USAMRAA on 10/28/93 Mod 3 – changed in task order deliverables (02/03/94) Mod 4 approved by USAMRAA on 10/19/94 Mod 5 approved by USAMRAA on 04/21/95	COMPLETED
PAGE TOTAL			\$401,879	\$32,633	\$434,512			

TASK NO.	PERIOD OF PERFORMANCE	DATE TASK APPROVED	AMOUNT OF ORDER	FIXED FEE	TOTAL	CUM TOTAL	DESCRIPTION	STATUS
9241 9241 Mod 1	1 Apr 1992 – 30 June 1992 1 Jul 1992 – 31 Dec 1992	17 Apr 1992 30 Sep 1992	\$17,023 \$10,127 \$27,150	\$1,329 \$786 \$2,115	\$18,352 \$10,913 \$29,265	\$3,324,090	TEP Mod 1 approved by USAMRAA on 09/30/92	COMPLETED
9242	1 May 1992 – 30 Jun 1992	4 May 1992	\$5,044	\$394	\$5,438	\$3,329,528	TEP	COMPLETED
9243	1 May 1992 – 30 Jul 1992	7 May 1992	\$4,465	\$349	\$4,814	\$3,334,342	TEP	COMPLETED
9244 9244 Mod 1	6 June 1992 – 30 Nov 1992	10 Jul 1992 7 Jul 1993	\$92,355 \$0 \$92,355	\$7,182 \$0 \$7,182	\$99,537 \$0 \$99,537	\$3,433,879	TEP USAMRAA cancelled future work – 6/7/93	CANCELLED
9245 9245 Mod 1 9245 Mod 2 9245 Mod 3	1 Aug 1992 – 3 Aug 1993	31 Jul 1992 29 Sep 1992 29 Sep 1992 3 Feb 1993 14 Jun 1993	\$51,079 \$16,784 \$78,056 \$0 \$0 \$145,919	\$3,972 \$1,305 \$6,056 \$0 \$0 \$11,333	\$55,051 \$18,089 \$84,112 \$0 \$0 \$157,252	\$3,591,131	TEP Mod 1 (Phase 1) telephonic approval received 9/30/92 Mod 1 (Phase 2) telephonic approval received 9/30/92 Initial scope of work proposed was changed USAMRAA discontinued task – 6/14/93	DISCONTINUED
9246 9246 Mod 1	15 Jul 1992 – 31 Jan 1993 15 Jul 1992 – 28 Feb 1995	13 Aug 1992 08 Feb 1995	\$21,149 (\$6,500) \$14,649	\$1,645 \$0 \$1,645	\$22,794 (\$6,500) \$16,294	\$3,607,425	TEP Task cancelled and \$6.5K deobligated	CANCELLED
9247	15 Aug 1992 – 31 Dec 1992	18 Nov 1992	\$22,692	\$1,761	\$24,453	\$3,631,878	TEP approved on 11/18/92	COMPLETED
9248	1 Sep 1992 – 31 Dec 1992	10 Sept 1992	\$34,936	\$2,710	\$37,646	\$3,669,524	TEP	COMPLETED
9249 9249 Mod 1 9249 Mod 2 9249 Mod 3 9249 Mod 4 9249 Mod 5 9249 Mod 6 9249 Mod 7 9249 Mod 8	1 Oct 1992 – 30 Sep 1993 1 Oct 1992 – 30 Sep 1993 1 Oct 1992 – 30 Sep 1993 1 Oct 1992 – 30 Sep 1993 1 Oct 1992 – 31 Oct 1993 1 Oct 1992 – 31 Jan 1994 1 Oct 1992 – 30 Apr 1994 1 Oct 1992 – 30 Apr 1994 1 Oct 1992 – 30 Apr 1994	22 Oct 1992 4 Mar 1993 7 Apr 1993 24 Aug 1993 12 Oct 1993 10 Nov 1993 26 Jan 1994 22 Feb 1994 2 Jun 1994	\$163,072 \$31,075 \$51,987 \$20,317 \$67,889 \$113,064 \$83,364 \$61,378 \$36,197 \$628,343	\$12,652 \$2,411 \$4,034 \$1,606 \$5,404 \$9,000 \$6,636 \$4,885 \$2,795 \$49,423	\$175,724 \$33,486 \$56,021 \$21,923 \$73,293 \$122,064 \$90,000 \$66,263 \$38,992 \$677,766	\$4,347,290	TEP approved on 10/22/92 Mod 1 approved on 03/04/93 Mod 2 approved on 04/07/93 Mod 3 approved on 08/25/93 Mod 4 telephonic approval received – 10/13/93 Mod 5 approved on 11/10/93 Mod 6 approved on 01/26/94 Mod 7 – remaining funds required in Mod 6 – 2/22/94 Revised Mod 8 approved on 06/02/94	COMPLETED
PAGE TOTAL			\$975,553	\$76,912	\$1,052,465			

TASK NO.	PERIOD OF PERFORMANCE	DATE TASK APPROVED	AMOUNT OF ORDER	FIXED FEE	TOTAL	CUM. TOTAL	DESCRIPTION	STATUS
9350 9350 Mod 1 9350 Mod 2	6 Nov 1992 – 28 Feb 1993	9 Dec 1992 8 Jul 1994 19 Oct 1994	\$18,329 \$11,647 \$0	\$1,422 \$899 \$0	\$19,751 \$12,546 \$0	\$4,379,587	TEP approved on 12/9/92 Mod 1 approved on 7/8/94 Task cancelled	CANCELLED
9351 9351 Mod 1 9351 Mod 2 9351 Mod 3 9351 Mod 4 9351 Mod 5	1 Feb 1993 – 30 June 1993 1 Feb 1993 – 28 Sept 1994 1 Feb 1993 – 30 March 1995 1 Feb 1993 – 30 March 1995 1 Feb 1993 – 30 March 1995 2 May 1995 25 May 1995	2 Feb 1993 7 Jun 1994 18 Nov 1994 21 Dec 1994 2 May 1995 25 May 1995	\$33,763 \$10,401 \$19,457 \$23,122 \$143 \$1,028 \$87,915	\$2,619 \$803 \$1,490 \$1,771 \$0 \$0 \$6,683	\$36,382 \$11,204 \$20,947 \$24,893 \$143 \$1,028 \$94,598	\$4,474,185	TEP approved on 02/2/93 Mod 1 approved on 06/7/94 Mod 2 approved by USAMRAA on 11/18/94 Mod 3 approved by USAMRAA on 12/21/94 Additional funding to accommodate cost growth of task Additional funding to accommodate cost growth of task	COMPLETED
9352	26 Apr 1993 – 15 Jul 1993	28 Apr 1992	\$17,235	\$1,372	\$18,607	\$4,492,792	TEP approved on 04/28/93	COMPLETED
9453 9453 Mod 1	1 Nov 1993 – 30 Jun 1995	8 Nov 1993 13 Jul 1995	\$14,002 (\$3,000) \$11,002	\$1,114 \$0 \$1,114	\$15,116 (\$3,000) \$12,116	\$4,504,908	TEP approved on 11/8/93 Task cancelled and \$3K deobligated	CANCELLED
9454 9454 Mod 1	15 Nov 1993 – 28 Sep 1994 15 Nov 1993 – 30 Mar 1995	18 Nov 1993 24 Feb 1995	\$80,570 (\$8,000) \$72,570	\$6,413 \$0 \$6,413	\$86,983 (\$8,000) \$78,983	\$4,583,891	TEP approved on 11/18/93 Task cancelled and \$8K deobligated	CANCELLED
9455	15 Feb 1994 – 28 Sep 1994	8 Mar 1994	\$22,594	\$1,798	\$24,392	\$4,608,283	Telephonic approval received on 3/08/94	COMPLETED
9456 9456 Mod 1 9456 Mod 2 9456 Mod 3	1 Mar 1994 – 28 Sep 1994 1 Mar 1994 – 30 Mar 1995 31 Mar 1995 – 30 Jun 1995 31 Mar 1995 – 30 Jun 1995	25 Mar 1994 14 Mar 1995 16 Mar 1995 31 May 1995	\$83,961 \$40,368 \$33,549 \$20,516 \$178,394	\$6,483 \$3,092 \$2,569 \$1,571 \$13,715	\$90,444 \$43,460 \$36,118 \$22,087 \$192,109	\$4,800,392	TEP approved on 03/25/94 Mod 1 approved on 03/14/95 Mod 2 approved on 03/16/95 Mod 3 approved on 05/31/95	COMPLETED
PAGE TOTAL			\$419,686	\$33,416	\$453,102			

TASK NO.	PERIOD OF PERFORMANCE	DATE TASK APPROVED	AMOUNT OF ORDER	FIXED FEE	TOTAL	CUM TOTAL	DESCRIPTION	STATUS
9457 9457 Mod 1	1 Apr 1994 - 30 Jun 1995 31 Mar 1995 - 30 Jun 1995	27 May 1994 18 May 1995	\$115,521 \$54,337 \$169,858	\$8,919 \$4,161 \$13,080	\$124,440 \$58,498 \$182,938	\$4,983,330	TEP approved on 05/27/94 Mod 1 approved on 05/18/95	COMPLETED
9458	13 Jun 1994 - 28 Sep 1994	30 Jun 1994	\$11,421	\$882	\$12,303	\$4,995,633	TEP approved on 6/30/94	COMPLETED
9459 9459 Mod 1	1 Aug 1994 - 30 Mar 1995 1 Aug 1994 - 30 Mar 1995	31 Aug 1994 7 Feb 1995	\$51,088 (\$4,644) \$46,444	\$3,912 (\$356) \$3,556	\$55,000 (\$5,000) \$50,000	\$5,045,633	TEP approved on 8/31/94, remaining funds (\$14,530) will be provided when available Task cancelled and \$5K deobligated	CANCELLED
PAGE TOTAL			\$227,723	\$17,518	\$245,241			
TOTAL APPROVED TASKS FUNDING →→→			\$4,673,836	\$371,797	\$5,045,633			

**DRAFT**

**ATTACHMENT 3**

**SUMMARY OF LABOR PROVIDED BY LABOR CATEGORY  
FOR EACH TASK**

# ATTACHMENT 3

## Summary of Labor Provided By Labor Category For Each Task

For the Period Ending: 07/28/95

CUMULATIVE-TO-DATE HOURS					
AMR TASK	MANAGER/ SR TECH	TECH	CLER	CONSULT/ SUBCONT	TOTAL
8901	4,201.5	3,688.5	2,727.8	10	10,627.8
8902	497.5	3,734.0	128.3	21	4,380.8
9003	1,382.5	2,258.0	620.0	34.5	4,295.0
9004*	24.0	6.5	17.0	0.0	47.5
9005	91.5	0.0	26.0	0.0	117.5
9006	208.0	2.0	81.8	0.0	291.8
9007	20.5	1.0	11.5	0.0	33.0
9008	189.5	1.0	111.3	0.0	301.8
9009	105.0	6.0	72.8	0.0	183.8
9010	83.0	1.0	102.3	0.0	186.3
9011	0.0	0.5	3.0	0.0	3.5
9012	230.5	247.0	137.0	0.0	614.5
9113	224.5	30.5	215.3	0.0	470.3
9114	143.0	2.0	117.5	0.0	262.5
9115	372.0	46.5	69.8	0.0	488.3
9116	25.5	0.5	10.3	0.0	36.3
9117	228.5	28.5	115.3	0.0	372.3
9118	148.0	1.0	117.5	0.0	266.5
9119	77.5	22.5	42.8	0.0	142.8
9120	47.0	2.0	16.8	0.0	65.8
9121	136.5	29.0	116.8	0.0	282.3
9122	279.0	763.0	223.8	0.0	1,265.8
9123	209.5	33.5	89.0	0.0	332.0
9124	7.0	1.0	1.0	0.0	9.0
9125	213.0	78.5	32.5	7783.4	8,107.4
9126	209.0	29.0	77.0	0.0	315.0
9127	149.0	11.5	54.5	0.0	215.0
9228	75.0	5.0	17.0	0.0	97.0
9229	133.0	23.5	61.0	0.0	217.5
9230	24.5	99.0	1.0	0.0	124.5
9231	26.0	15.0	81.5	0.0	122.5
9232	175.0	6.0	9.5	0.0	190.5
9233	70.0	83.0	21.5	8.5	183.0
9234	29.0	1.0	0.0	0.0	30.0
9235	432.0	439.5	226.0	1199	2,296.5
9236	56.5	42.0	6.0	0.0	104.5
9237	46.5	26.0	39.3	0.0	111.8
9238	32.5	3.5	26.0	0.0	62.0
9239	151.0	29.5	93.0	0.0	273.5
9240	60.5	475.0	60.5	0.0	596.0
9241	231.0	93.0	101.0	0.0	425.0
9242	43.5	14.0	2.0	0.0	59.5
9243	35.0	4.5	28.5	0.0	68.0
9244	64.5	10.5	18.0	605.5	698.5
9245	556.5	1,481.5	454.5	142.5	2,635.0
9246	132.5	1.5	1.0	0.0	135.0
9247	38.5	14.0	59.0	276	387.5
9248	14.0	16.0	43.0	99.5	172.5
9249	1,503.0	2,825.0	2,491.5	2051.25	8,870.8
9350	271.0	13.5	43.5	0.0	328.0
9351	126.0	1,080.8	220.5	308.75	1,736.0
9352	130.5	17.5	67.5	0.0	215.5
9453	81.5	0.0	22.0	0.0	103.5
9454	83.0	790.0	112.5	255	1,240.5
9455	192.5	14.5	67.5	0.0	274.5
9456	1,116.0	506.5	336.5	40	1,999.0
9457	990.0	886.5	383.0	40	2,299.5
9458	90.5	2.5	12.5	0.0	105.5
9459	327.5	142.5	87.5	0.0	557.5
TOTAL	16,841.0	20,186.8	10,530.8	12,874.9	60,434.4

\*Subcontractor (3M Pharmaceuticals) labor hours not available.

**DRAFT**

**ATTACHMENT 4**

**COST TOTALS FOR EACH TASK BY ELEMENT OF EXPENSE**



# ATTACHMENT 4

## COST TOTALS FOR EACH TASK BY ELEMENT OF EXPENSE For the Period Ending: 07/28/95

EER TASK No.	Direct Labor	Overhead	Premium	Consultants	Travel	ODC's	G&A	Subs & T. Members	Direct Materials	S & M Handling	Fee	Cumulative Totals
AMR02-01	\$267,286.66	\$239,600.55	\$106.62	\$18,755.42	\$3,866.36	\$36,189.43	\$57,187.09	\$441.84	\$0.00	\$18.93	\$42,484.10	\$685,937.00
AMR02-02	\$86,703.31	\$77,735.14	\$7.33	\$3,504.75	\$278.97	\$5,668.28	\$17,773.64	\$0.00	\$56.67	\$1.77	\$12,672.94	\$204,402.80
AMR02-03	\$105,052.46	\$94,019.74	\$0.00	\$11,195.59	\$645.36	\$10,349.49	\$22,724.40	\$243.74	\$0.00	\$8.22	\$16,272.52	\$260,511.52
AMR02-04	\$1,113.65	\$975.82	\$0.00	\$104,632.99	\$0.00	\$20.69	\$10,647.59	(\$2,132.00)	\$0.00	(\$79.74)	\$9,168.91	\$124,347.92
AMR02-05	\$4,904.00	\$4,295.14	\$0.00	\$379.05	\$0.00	\$69.92	\$933.54	\$0.00	\$0.00	\$0.00	\$842.30	\$11,423.95
AMR02-06	\$12,250.28	\$10,732.44	\$0.00	\$1,050.43	\$22.80	\$248.07	\$2,344.49	\$0.00	\$0.00	\$0.00	\$2,121.22	\$28,769.73
AMR02-07	\$1,173.50	\$1,024.82	\$0.00	\$197.55	\$0.00	\$4.00	\$241.19	\$0.00	\$0.00	\$0.00	\$210.23	\$2,851.28
AMR02-08	\$9,983.88	\$8,718.92	\$0.00	\$1,881.47	\$100.56	\$71.30	\$2,085.99	\$0.00	\$0.00	\$0.00	\$1,818.23	\$24,660.36
AMR02-09	\$5,942.51	\$5,189.59	\$0.00	\$1,281.56	\$179.92	\$376.51	\$1,303.49	\$0.00	\$0.00	\$0.00	\$1,136.18	\$15,409.77
AMR02-10	\$4,089.76	\$3,571.59	\$0.00	\$1,733.69	\$89.79	\$610.26	\$1,014.56	\$0.00	\$0.00	\$0.00	\$884.33	\$11,993.97
AMR02-11	\$8.00	\$6.99	\$0.00	\$50.85	\$0.00	\$6.64	\$7.28	\$0.00	\$0.00	\$0.00	\$6.35	\$86.11
AMR02-12	\$19,045.30	\$17,153.07	\$0.00	\$209.43	\$0.00	\$923.23	\$3,638.48	\$0.00	\$0.00	\$0.00	\$3,261.17	\$44,230.69
AMR02-13	\$11,914.15	\$10,466.87	\$0.00	\$3,425.58	\$99.26	\$965.21	\$2,682.15	\$0.00	\$0.00	\$0.00	\$2,352.44	\$31,905.66
AMR02-14	\$8,266.99	\$7,219.56	\$5.90	\$1,213.50	\$65.56	\$642.33	\$1,748.81	\$0.00	\$0.00	\$0.00	\$1,525.35	\$20,688.00
AMR02-15	\$18,741.95	\$16,439.48	\$8.84	\$489.65	\$238.64	\$1,267.64	\$3,787.66	\$0.00	\$0.00	\$0.00	\$3,125.97	\$44,099.83
AMR02-16	\$1,538.00	\$1,343.14	\$0.00	\$181.13	\$14.40	\$261.28	\$335.46	\$0.00	\$0.00	\$0.00	\$292.40	\$3,965.81
AMR02-17	\$12,876.89	\$11,291.83	\$26.56	\$660.94	\$94.89	\$1,087.58	\$2,599.67	\$0.00	\$0.00	\$0.00	\$2,279.61	\$30,917.98
AMR02-18	\$6,255.31	\$5,462.76	\$0.00	\$2,027.97	\$78.48	\$1,152.94	\$1,505.23	\$0.00	\$0.00	\$0.00	\$1,312.02	\$17,794.72
AMR02-19	\$4,582.22	\$3,999.80	\$0.00	\$741.21	\$48.02	\$406.18	\$983.12	\$0.00	\$0.00	\$0.00	\$856.54	\$11,617.10
AMR02-20	\$2,000.11	\$1,746.70	\$0.00	\$297.30	\$853.49	\$290.74	\$521.43	\$0.00	\$0.00	\$0.00	\$454.50	\$6,164.26
AMR02-21	\$7,428.40	\$6,540.87	\$0.00	\$1,754.16	\$32.75	\$327.17	\$1,601.71	\$0.00	\$0.00	\$0.00	\$1,407.73	\$19,092.78
AMR02-22	\$28,995.84	\$26,165.56	\$0.00	\$502.67	\$119.09	\$5,572.64	\$6,386.30	\$173.19	\$0.00	\$5.81	\$4,037.48	\$71,958.57
AMR02-23	\$9,676.25	\$8,741.76	\$14.63	\$79.13	\$113.57	\$1,458.18	\$1,933.30	\$0.00	\$0.00	\$0.00	\$1,752.54	\$23,769.36
AMR02-24	\$293.01	\$255.89	(\$0.11)	\$0.00	\$0.00	\$7.44	\$55.89	\$0.00	\$0.00	\$0.00	\$48.72	\$660.84
AMR02-25	\$10,117.86	\$9,020.78	\$0.00	\$603,936.25	\$2,948.92	\$154.66	\$60,356.78	\$0.00	\$0.00	\$0.00	\$54,027.97	\$740,563.22
AMR02-26	\$9,326.88	\$8,452.95	\$0.00	\$67.27	\$58.09	\$532.46	\$1,768.17	\$0.00	\$0.00	\$0.00	\$1,608.38	\$21,814.21
AMR02-27	\$6,625.43	\$6,004.63	\$0.00	\$0.00	\$7.80	\$276.18	\$1,241.33	\$0.00	\$0.00	\$0.00	\$1,129.16	\$15,314.53
AMR02-28	\$3,098.12	\$2,807.83	\$0.00	\$21.75	\$31.12	\$231.55	\$593.66	\$0.00	\$0.00	\$0.00	\$540.01	\$7,324.03
AMR02-29	\$6,261.95	\$5,675.21	\$0.00	\$0.00	\$32.20	\$260.68	\$1,172.86	\$0.00	\$0.00	\$0.00	\$1,066.87	\$14,469.77
AMR02-30	\$2,813.94	\$2,550.27	\$0.00	\$7.47	\$0.00	\$120.46	\$526.70	\$0.00	\$0.00	\$0.00	\$479.10	\$6,497.94
AMR02-31	\$2,202.81	\$1,996.41	\$67.18	\$36.75	\$0.00	\$1,470.64	\$553.71	\$0.00	\$0.00	\$0.00	\$503.67	\$6,831.16
AMR02-32	\$7,885.04	\$6,861.81	\$0.00	\$0.00	\$0.00	\$115.37	\$1,560.53	\$0.00	\$0.00	\$0.00	\$621.81	\$17,044.56
AMR02-33	\$5,160.48	\$4,676.94	\$0.00	\$1,062.50	(\$10.00)	\$281.49	\$1,071.29	\$0.00	\$0.00	\$0.00	\$974.78	\$13,217.48
AMR02-34	\$1,218.69	\$1,085.98	\$0.00	\$0.00	\$0.00	\$11.84	\$230.90	\$0.00	\$0.00	\$0.00	\$202.77	\$2,750.19
AMR02-35	\$25,845.91	\$23,424.15	\$35.37	\$159,535.24	\$4,308.36	\$1,357.78	\$20,571.20	\$0.00	\$0.00	\$0.00	\$18,712.21	\$253,790.22
AMR02-36	\$3,264.36	\$2,356.99	\$0.00	\$131.63	\$0.00	\$17.32	\$660.85	\$0.00	\$0.00	\$0.00	\$601.13	\$8,153.01
AMR02-37	\$2,600.67	\$2,356.99	\$0.00	\$37.18	\$0.00	\$369.79	\$523.53	\$0.00	\$0.00	\$0.00	\$476.22	\$6,458.82
AMR02-38	\$1,648.67	\$1,494.19	\$11.79	\$37.18	\$0.00	\$449.98	\$345.68	\$0.00	\$0.00	\$0.00	\$314.44	\$4,264.76
AMR02-39	\$7,319.27	\$6,633.45	\$8.84	\$37.18	\$0.00	\$869.39	\$1,425.85	\$0.00	\$0.00	\$0.00	\$1,297.00	\$17,590.99
AMR02-40	\$12,596.97	\$11,374.93	\$0.00	\$9.07	\$26.00	\$792.01	\$2,621.57	\$150.79	\$0.00	\$4.80	\$1,483.19	\$29,059.33
AMR02-41	\$12,386.82	\$11,226.17	\$0.00	\$7.48	\$138.42	\$1,427.23	\$2,415.35	\$0.00	\$0.00	\$0.00	\$2,197.08	\$29,798.55

# ATTACHMENT 4

## COST TOTALS FOR EACH TASK BY ELEMENT OF EXPENSE (continued) For the Period Ending: 07/28/95

EER TASK No.	Direct Labor	Overhead	Premium	Consultants	Travel	ODC's	G&A	Subs & T. Members	Direct Materials	S. & M. Handling	Fee	Cumulative Totals
AMR02-42	\$2,198.64	\$1,992.63	\$0.00	\$0.00	\$61.15	\$27.12	\$410.41	\$0.00	\$0.00	\$0.00	\$373.32	\$5,063.26
AMR02-43	\$1,777.41	\$1,610.87	\$11.79	\$0.00	\$49.42	\$353.66	\$364.72	\$0.00	\$0.00	\$0.00	\$331.76	\$4,499.63
AMR02-44	\$2,949.93	\$2,644.92	\$0.00	\$45,798.00	\$507.08	\$134.20	\$5,051.91	\$0.00	\$0.00	\$0.00	\$4,388.31	\$61,474.35
AMR02-45	\$53,089.49	\$47,732.81	\$80.44	\$28,897.95	\$709.17	\$2,564.92	\$12,956.02	\$0.00	\$0.00	\$0.00	\$11,266.33	\$157,297.14
AMR02-46	\$6,164.32	\$5,563.70	\$0.00	\$0.00	\$142.55	\$44.16	\$1,211.32	\$0.00	\$0.00	\$0.00	\$759.62	\$13,885.67
AMR02-47	\$2,618.21	\$2,285.31	\$0.00	\$14,386.00	\$34.50	\$312.48	\$2,061.20	\$0.00	\$0.00	\$0.00	\$1,132.37	\$22,830.06
AMR02-48	\$1,610.90	\$1,459.96	\$23.81	\$13,035.14	\$0.00	\$500.92	\$1,595.01	\$0.00	\$0.00	\$0.00	\$1,450.77	\$19,676.50
AMR02-49	\$138,608.75	\$120,202.90	\$1,464.80	\$234,890.75	\$1,372.50	\$35,086.90	\$54,972.80	\$14,862.67	\$0.00	\$458.78	\$40,137.38	\$642,058.22
AMR02-50	\$12,792.66	\$11,475.30	\$0.00	\$0.00	\$0.00	\$395.92	\$2,595.92	\$855.92	\$0.00	\$40.63	\$1,794.56	\$29,950.92
AMR02-51	\$25,499.52	\$23,476.84	\$141.39	\$28,273.25	\$72.50	\$3,688.89	\$8,746.00	\$106.49	\$0.00	\$3.72	\$4,771.03	\$94,779.63
AMR02-52	\$6,986.20	\$6,074.50	\$0.00	\$0.00	\$0.00	\$442.36	\$1,420.52	\$0.00	\$0.00	\$0.00	\$44.56	\$14,968.14
AMR02-53	\$3,914.52	\$3,636.25	\$0.00	\$0.00	\$46.52	\$279.09	\$870.66	\$0.00	\$0.00	\$0.00	\$570.37	\$9,317.41
AMR02-54	\$21,604.93	\$20,123.12	\$28.41	\$23,463.45	\$172.35	\$2,821.95	\$7,445.54	\$197.62	\$0.00	\$6.19	\$2,707.53	\$78,571.08
AMR02-55	\$9,814.88	\$8,395.87	\$24.01	\$0.00	\$53.50	\$799.19	\$1,934.51	\$75.38	\$0.00	\$2.36	\$1,216.36	\$22,316.06
AMR02-56	\$60,119.15	\$57,017.45	\$73.86	\$2,590.57	\$1,003.82	\$2,355.44	\$13,729.15	\$945.50	\$0.00	\$43.73	\$9,587.59	\$147,466.26
AMR02-57	\$56,248.39	\$54,280.77	\$44.76	\$6,513.73	\$420.00	\$2,589.81	\$13,655.50	\$2,022.53	\$0.00	\$95.50	\$6,746.43	\$142,617.42
AMR02-58	\$4,283.89	\$4,056.42	\$0.00	\$0.00	\$1,739.26	\$110.64	\$1,119.90	\$54.70	\$0.00	\$2.61	\$729.07	\$12,096.48
AMR02-59	\$18,751.41	\$17,755.71	\$2.84	\$0.00	\$223.25	\$1,423.29	\$4,193.94	\$0.00	\$0.00	\$0.00	\$1,511.04	\$43,861.48
<b>TOTAL</b>	<b>\$1,179,866.99</b>	<b>\$1,061,390.39</b>	<b>\$2,189.06</b>	<b>\$1,318,947.45</b>	<b>\$21,127.89</b>	<b>\$130,646.92</b>	<b>\$376,017.46</b>	<b>\$17,998.37</b>	<b>\$56.67</b>	<b>\$613.30</b>	<b>\$286,078.00</b>	<b>\$4,394,932.50</b>

**DRAFT**

**ATTACHMENT 5**

**SUMMARY OF FUNDS NEGOTIATED INCLUDING MODIFICATIONS  
COST INCURRED, AND PERCENTAGE OF  
PLANNED FUNDS EXPENDED BY TASK**

# ATTACHMENT 5

## SUMMARY OF FUNDS NEGOTIATED INCLUDING MODIFICATIONS COST INCURRED AND PERCENTAGE OF PLANNED FUNDS EXPENDED BY TASK AS OF 28 JULY 1995

TASK NO.	ORIG. FUNDS NEGOTIATED	ADDT'L FUNDS NEGOTIATED	TOTAL FUNDS NEGOTIATED	CUM COST INCURRED	(%) \$ EXPENDED	STATUS
8901 Mod 1 Mod 2 Mod 3 Mod 4	\$387,409	\$115,585 \$118,944 \$52,033 \$30,677	\$704,648	\$665,937	94.51%	In-progress (as of 07/28/95)
8902 Mod 1 Mod 2 Mod 3 Mod 4	\$113,547	\$33,913 \$35,691 \$23,133 \$12,224	\$218,508	\$204,403	93.54%	Completed
9003 Mod 2 Mod 3 Mod 4 Mod 5	\$327,343	(\$140,000) \$52,195 \$23,642 \$16,395	\$279,575	\$260,512	93.18%	Completed
9004	\$207,323		\$207,323	\$124,348	59.98%	Completed
9005	\$40,972		\$40,972	\$11,424	27.88%	Cancelled
9006	\$40,972		\$40,972	\$28,770	70.22%	Cancelled
9007	\$6,250		\$6,250	\$2,851	45.62%	Completed
9008 Mod 1 Mod 2	\$6,683	\$17,342 \$1,766	\$25,791	\$24,660	95.62%	Completed
9009 Mod 1	\$32,334	\$2,644	\$34,978	\$15,410	44.06%	Completed
9010	\$32,362		\$32,362	\$11,994	37.06%	Completed
9011	\$16,047		\$16,047	\$86	0.54%	Cancelled
9012 Mod 1 Mod 3 Mod 4	\$18,317	\$9,377 \$8,725 \$7,153	\$43,572	\$44,231	101.51%	Completed
9113 Mod 1 Mod 2 Mod 3	\$20,309	\$3,538 \$6,190 \$2,548	\$32,585	\$31,906	97.92%	Completed
9114 Mod 2	\$18,627 —	\$4,797	\$23,424	\$20,688	88.32%	Completed

# ATTACHMENT 5

## SUMMARY OF FUNDS NEGOTIATED INCLUDING MODIFICATIONS COST INCURRED AND PERCENTAGE OF PLANNED FUNDS EXPENDED BY TASK AS OF 28 JULY 1995 (cont'd)

TASK NO.	ORIG. FUNDS NEGOTIATED	ADD'T'L FUNDS NEGOTIATED	TOTAL FUNDS NEGOTIATED	CUM COST INCURRED	(%) \$ EXPENDED	STATUS
9115 Mod 2 Mod 3	\$23,915	\$15,360 \$6,501	\$45,776	\$44,100	96.34%	Completed
9116	\$24,378		\$24,378	\$3,966	16.27%	Cancelled
9117 Mod 1 Mod 2	\$18,627	\$11,007 \$4,299	\$33,933	\$30,918	91.11%	Completed
9118	\$20,643		\$20,643	\$17,795	86.20%	Completed
9119	\$16,633		\$16,633	\$11,617	69.84%	Completed
9120 Mod 1	\$19,733	\$1,870	\$21,603	\$6,164	28.53%	Cancelled
9121 Mod 1 Mod 3	\$10,269	\$7,624 \$2,548	\$20,441	\$19,093	93.40%	Completed
9122 Mod 1 Mod 2 Mod 3 Mod 5 Mod 6	\$23,426	\$5,912 \$17,380 \$20,341 \$9,643 \$5,538	\$82,240	\$71,959	87.50%	Completed
9123	\$25,832		\$25,832	\$23,769	92.02%	Completed
9124	\$25,832		\$25,832	\$661	2.56%	Cancelled
9125 Mod 1 Mod 2 Mod 3 Mod 4 Mod 5 Mod 6	\$493,916	\$10,187 \$21,262 \$43,551 \$116,381 \$179,845 (\$100,000)	\$765,142	\$740,563	96.79%	Cancelled
9126	\$23,241		\$23,241	\$21,814	93.86%	Completed
9127	\$16,487		\$16,487	\$15,315	92.89%	Completed
9228	\$8,129		\$8,129	\$7,324	90.10%	Completed
9229	\$15,187		\$15,187	\$14,470	95.28%	Completed

# ATTACHMENT 5

## SUMMARY OF FUNDS NEGOTIATED INCLUDING MODIFICATIONS COST INCURRED AND PERCENTAGE OF PLANNED FUNDS EXPENDED BY TASK AS OF 28 JULY 1995 (cont'd)

TASK NO.	ORIG. FUNDS NEGOTIATED	ADD'L FUNDS NEGOTIATED	TOTAL FUNDS NEGOTIATED	CUM COST INCURRED	(%) \$ EXPENDED	STATUS
9230 Mod 1	\$2,391	\$5,418	\$7,809	\$6,498	83.21%	Completed
9231	\$9,185		\$9,185	\$6,831	74.37%	Completed
9232	\$24,884		\$24,884	\$17,045	68.50%	Completed
9233	\$14,312		\$14,312	\$13,217	92.35%	Completed
9234	\$14,060		\$14,060	\$2,750	19.56%	Completed
9235 Mod 1 Mod 2	\$42,335	\$217,256 \$5,379	\$264,970	\$253,790	95.78%	Completed
9236	\$38,367		\$38,367	\$8,153	21.25%	Cancelled
9237	\$8,633		\$8,633	\$6,459	74.82%	Completed
9238	\$8,633		\$8,633	\$4,265	49.40%	Completed
9239	\$17,726		\$17,726	\$17,591	99.24%	Completed
9240 Mod 1 Mod 2 Mod 4 Mod 5	\$6,192	\$8,827 \$10,635 \$5,277 \$2,811	\$33,742	\$29,059	86.12%	Completed
9241 Mod 1	\$18,352	\$10,913	\$29,265	\$29,799	101.82%	Completed
9242	\$5,438		\$5,438	\$5,063	93.11%	Completed
9243	\$4,814		\$4,814	\$4,500	93.47%	Completed
9244	\$99,537		\$99,537	\$61,474	61.76%	Cancelled
9245 Mod 1	\$55,051	\$102,201	\$157,252	\$157,297	100.03%	Discontinued
9246 Mod 1	\$22,794	(\$6,500)	\$16,294	\$13,886	85.22%	Cancelled
9247	\$24,453		\$24,453	\$22,830	93.36%	Completed

# ATTACHMENT 5

## SUMMARY OF FUNDS NEGOTIATED INCLUDING MODIFICATIONS COST INCURRED AND PERCENTAGE OF PLANNED FUNDS EXPENDED BY TASK AS OF 28 JULY 1995 (cont'd)

TASK NO.	ORIG. FUNDS NEGOTIATED	ADD'L FUNDS NEGOTIATED	TOTAL FUNDS NEGOTIATED	CUM COST INCURRED	(%) \$ EXPENDED	STATUS
9248	\$37,646		\$37,646	\$19,677	52.27%	Completed
9249 Mod 1 Mod 2 Mod 3 Mod 4 Mod 5 Mod 6 Mod 7 Mod 8	\$175,724	\$33,486 \$56,021 \$21,923 \$73,293 \$122,064 \$90,000 \$66,263 \$38,992	\$677,766	\$642,058	94.73%	Completed
9350 Mod 1	\$19,751	\$12,546	\$32,297	\$29,950	92.73%	Cancelled
9351 Mod 1 Mod 2 Mod 3 Mod 4 Mod 5	\$36,382	\$11,204 \$20,947 \$24,893 \$143 \$1,028	\$94,598	\$94,780	100.19%	Completed
9352	\$18,607		\$18,607	\$14,968	80.44%	Completed
9453 Mod 1	\$15,116	(\$3,000)	\$12,116	\$9,317	76.90%	Cancelled
9454 Mod 1	\$86,983	(\$8,000)	\$78,983	\$78,571	99.48%	Cancelled
9455	\$24,392		\$24,392	\$22,316	91.49%	Completed
9456 Mod 1 Mod 2 Mod 3	\$90,444	\$43,460 \$36,118 \$22,087	\$192,109	\$147,466	76.76%	Completed
9457 Mod 1	\$124,440	\$58,498	\$182,938	\$142,617	77.96%	Completed
9458	\$12,303		\$12,303	\$12,096	98.32%	Completed
9459 Mod 1	\$55,000	(\$5,000)	\$50,000	\$43,861	87.72%	Cancelled
TOTALS	\$3,148,688	\$1,896,944	\$5,045,633	\$4,394,933	87.10%	